

**PSYCHOLOGICAL AND CLINICAL PREDICTORS OF COMPLIANCE
WITH CONTINUOUS POSITIVE AIRWAY PRESSURE THERAPY FOR
OBSTRUCTIVE SLEEP APNOEA: A PROSPECTIVE STUDY**

and Research Portfolio

Part One

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Submitted in partial fulfilment toward the degree of
Doctorate of Clinical Psychology

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Dedicated to my family and friends



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CHAPTER 1

SMALL SCALE SERVICE EVALUATION PROJECT

The Provision of Clinical Psychology Services Within a General Hospital: An Analysis and Interpretation of Referral Rates

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Prepared in accordance with guidelines for submission to
Health Bulletin (Appendix 1.1)

ABSTRACT

Objectives

To assess the level of knowledge and understanding, among healthcare professionals, about the activities of clinical psychologists and to assess perception of need for the clinical psychology service within a general hospital. Differences between high/regular and occasional/non-referring departments were examined in relation to the above objectives with a view towards explaining variations in referral rates to the Department of Clinical Psychology.

Design and Subjects

A semi-structured interview, containing items aimed at addressing the above objectives, was administered to fifteen hospital based medical and surgical consultants representing different departments.

Setting

A General Hospital in Central Scotland

Results

High/regular referring departments displayed a greater level of knowledge and understanding of clinical psychology practice than occasional/non-referring departments. The occasional/non-referring departments demonstrated more cautious attitudes than high/regular referring departments towards psychological input to the care of patients. Overall, most departments indicated that they would be interested in learning more about the clinical psychology service and what it could offer their departments.

Conclusions

The study identified a generally low level of awareness and understanding of psychological issues among the departmental representatives within the general hospital. This highlighted the need for education about the role of clinical psychology in general hospitals and improved communication between the psychology service and other departments in the hospital. The survey identified that these moves would generally be welcomed by departments, suggesting that lower referral rates were more likely to be a result of poor understanding rather than hostility or mistrust towards psychological methods. A larger scale study should be carried out to investigate the generality of these findings.

INTRODUCTION

Clinical psychologists have the potential to contribute to the treatment of psychological and behavioural aspects of diseases in virtually all major medical specialities (Groth-Marnet, 1988). In recent years the UK has seen a significant expansion in the role of psychologists within general hospitals (Clifford, 1989). Despite this, clinical psychologists continue to be seen by other health care professions as a "virtually unknown group" (Osborne-Davies, 1996). Hence, a marketing task is required for the profession to ensure that the effectiveness of clinical psychology reaches its audiences (Chadd & Svanberg, 1994).

Perception of need is an important factor in referral rates, but is of particular consequence within the environment of general medicine and surgery. The biomedical model of care has predominated in these areas of medicine, potentially promoting passivity in the patient. This purely biomedical approach is often ineffective in treating a range of physical disorders, as many patients seek medical services for problems which are psychologically based (Schwartz, 1982). In contrast, clinical psychology aims to introduce more psychosocially oriented management which may conflict with traditional medical practice within the NHS (Broome & Llewelyn, 1995). This conflict is generally considered to occur through a lack of understanding of psychological practice (Bamgbose et al, 1980).

The attitudes and behaviours of health professionals have been observed to be influenced by expectations regarding health problems (McGee, 1997). A number of studies have reported the underdiagnosis of mental health problems in patients with physical disorders (Lopez, 1989). This suggests that some carers consider physical and psychological health problems to be distinct from each other, perhaps illustrating that those with both types of problem may be underserved by the current approach adopted by some health professionals. Perception of need has also been implicated in health outcomes. Marteau (1996) suggested that physician's perceptions may impact on outcome by effecting the

patient's cognitions and behaviour, or by altering medical procedures and treatments as a result of their beliefs.

Fundamentally, there is a need to examine ways of improving psychological care within the setting of the general hospital. By moving away from traditional biomedical models of care it may be possible to establish a system which identifies and addresses the psychological needs of the patient. McGee (1997) suggests that further study of the attitudes of health professionals is necessary to counterbalance previous attention made to the attitudes of service users. If included in a wider research agenda, this may positively influence the individual professional's understanding of their role, thereby improving the delivery of health services in the future.

In this study medical and surgical consultants were asked, by means of a semi-structured interview, about the clinical psychology service offered to departments within a general hospital. The Department of Clinical Psychology, the focus of this study, has offered psychological services to medical and surgical departments for fifteen years. The service is well established and referrals are regularly received from a number of departments. However, not all departments refer, so it was the primary aim of this study to examine why certain areas of medicine were not utilising the service. Further aims included;

- (1) To differentiate between high/regular and occasional/non-referring departments on the basis of referral patterns and the decision factors involved in referral and non-referral.
- (2) To assess the level of knowledge about clinical psychology and the clinical psychology service, among departmental representatives, and to investigate their level of understanding of psychological practice. It was hypothesised that high/regular referring departments would demonstrate a higher level of knowledge and understanding than low/non-referring departments.

(3) To examine the perception of present and future need for a psychology service, as reported by potential referrers within the hospital. It was hypothesised that high/regular referring departments would report a greater perceived need for the service and would demonstrate a greater level of acceptance for psychological input to the care of patients.

METHODS

Participants

All nominated departmental representatives were hospital based consultants (n = 15) with a mean of twelve years experience at that level of practice.

Materials

A semi-structured interview (Appendix 1.2) was developed for this study and was not based on any standardised measurements. Items were included which related to relevant literature and which were felt appropriate to the aims of the study. This eighteen item interview included Likert type, categorical and open ended questions. These items aimed to examine referral patterns and processes, common perceptions about clinical psychology and the service it provides to medicine and surgery at present and in the future. The study was interview based so as to avoid the problem of low response rates often associated with questionnaire based surveys. The interview also gave participants an opportunity to offer additional information and discuss issues relating to the provision of the clinical psychology service in more depth.

Procedure

A letter (Appendix 1.3) was sent to the chief consultant of each medical and surgical department in the hospital (n = 15). This asked them to nominate a departmental representative to be involved in a study examining attitudes and perceptions of need towards the service offered by the Department of Clinical Psychology. The letter also stated that the representative was required to have knowledge of referral practices within

the department. This letter was followed up by a telephone call to arrange a suitable time to meet with the departmental representative. All participants were met in their own departments and each interview took an average of twenty minutes to complete. Prior to administration of the interview all participants were sent the same information and instructions (Appendix 1.4).

All departments in the hospital, apart from the radiology department, have at some time referred to the service. Over recent years referrals have displayed two distinct patterns, that of high/regular referrers (H/R) and occasional/non-referrers (O/N). In order to address the aims of this study these departments were allocated to one of these two groups. This was conducted by examining the numbers of referrals made by all departments during the year prior to the present study (i.e. 1997) (Appendix 1.5). The median number of referrals per year was then calculated (median = 1 referral). Those departments above the median were placed in the high/regular referring group (H/R), and those below were allocated to the occasional/non-referring group (O/N). The median was used rather than the mean to select the groups as the range of numbers of referrals was large (0-31) and the mean may be skewed by these outlying variables. All those in the O/N group were asked question 7 (Q7; Appendix 1.2) in addition to the other items in the interview.

Following this process the two groups, H/R and O/N, comprised seven and eight participants respectively. Departments in the H/R group comprised; Infectious diseases, neurology, gynaecology, anaesthetics, haematology, general surgery and general medicine. The O/N group comprised the following departments; Radiology, accident and emergency, dermatology, orthopaedics, urology, cardiology, renal and ear, nose and throat (ENT).

RESULTS

Referral Patterns and Processes Reported by Departments

All representatives were aware that a psychological service was available to all departments within the hospital. Three departments (20%) reported that they had become aware of the service because they had specifically looked for it, the remainder (80%) could not recall how they became aware of the service. Half of the O/N group said that they would not refer to the department. The remaining four departments in that group reported they would refer 1-5 patients to the service each year. In the H/R group 28.6% identified 16-20 as their most representative referral rate. The same number of representatives identified 6-10, and the remaining 42.8% opted for 1-5. Of those in the O/N group that said they referred, none believed that they were making full use of the service. Reasons for this included an awareness of limited resources in the clinical psychology service and a lack of psychological understanding among colleagues (e.g. one consultant said, "If they can't operate, they don't want to know"). In the H/R group three of the seven representatives reported that their perception of a long waiting list prevented them from making full use of the service.

Question 7 was only administered to participants in the O/N group. Results from this item indicated that all eight participants identified, as reasons for non-referral, a lack of information about the service and about the role of clinical psychologists within the hospital. A quarter of the departments did not consider the service to be relevant to the care of medical and surgical patients, but all of those asked believed that clinical psychologists did have a role to play in the hospital. All occasional referring departments (n = 4) perceived the waiting list to be too long and six departments felt that they might consider referral to another agency before referring to clinical psychology. These other agencies most commonly included psychiatry or the patient's GP.

Table 1 shows that all participants in the O/N group considered "waiting times for treatment" and a "good outcome from previous referral" to be important in their decision

to refer to the service. There was a significant difference between the responses of the O/N group and the responses of the H/R group (waiting list, $\chi^2(1)=4.29$, $p < 0.05$; good outcome, $\chi^2(1)=4.29$, $p < 0.05$). Both groups identified the patient’s motivation to seek psychological support as important in their decision making process. The H/R group (n = 7) also believed that knowledge of a member from staff at the Department of Clinical Psychology was important.

Insert Table 1 here

Level of Knowledge and Understanding about Clinical Psychology Practice as Demonstrated by Departments

Respondents from both groups suggested that treatment of anxiety, depression, psychosexual difficulties and adjustment to life events were services offered by clinical psychologists (Appendix 1.6). Table 2 shows that the H/R group identified behavioural management as a service offered by clinical psychologists significantly more often than the O/N group ($\chi^2(1) = 4.77$, $p < 0.05$). All participants in the H/R group recognised that relaxation training was also offered by the service. Hypnotherapy and advice about medication (included as distracters) did not differentiate between the groups.

Insert Table 2 here

It can be seen in Table 3 that participants in the H/R group rated pain management and psychological preparation for physical treatment as significantly more relevant to their department than did the O/N group (pain, Mann-Whitney $U = 6.0$, $p < 0.05$; psychological preparation, $U = 6.5$, $p < 0.05$). Overall, behavioural management, adjustment to life events, neuropsychological assessment and relaxation techniques were rated highly relevant by the H/R group. A similar pattern was observed in the O/N group, although relevance ratings provided by these representatives were deflated.

Insert Table 3 here

Overall, both groups most commonly identified adjustment to life events ($n = 11$), behavioural management ($n = 13$), neuropsychological assessment ($n = 10$) and relaxation techniques ($n = 13$) as services offered by the Department of Clinical Psychology. They also consistently rated these services as highly relevant to their departments (adjustment, mean = 7.45, SD = 1.86; behavioural management, mean = 6.45, SD = 2.7; neuropsychological assessment, mean = 6.4, SD = 2.5; relaxation, mean = 7, SD = 2.2). The H/R group overall rated all services as significantly more relevant than did the O/N group ($U = 39$, $p < 0.01$). The overall mean relevance ratings for the H/R and O/N groups were 7.2 and 4.9 respectively. So, the H/R group identified more services provided by the Department of Clinical Psychology and rated them as more highly relevant to the care of patients in their departments than did the O/N group (Appendix 1.7).

Most participants in the H/R group (71.4%) reported that they would like to wait no longer than one month for a clinical psychologist to contact their patient following a routine referral. The remaining two (26.8%) participants were prepared to wait up to three months. For an urgent referral, most (71.4%) would not wait for more than one week. The remaining departments ($n=2$) would accept a wait of no more than one day. In the O/N group most (75%) would wait for up to one month following a routine referral. Two departments (25%) would accept a waiting list of up to three months. In terms of an urgent referral, three participants (37.5%) would like contact with a clinical psychologist within one day, and five (62.5%) would be prepared to wait for up to one week.

Perception of Need for a Psychological Service as Reported by Departments

The H/R group currently perceive the service as significantly more important to the care of their patients than the O/N group ($U = 9.5$, $p < 0.05$). In general most participants in the O/N group (75%) did not feel that they currently had enough information about the service, while most members of the H/R group (71.4%) felt that they did have enough

information. Despite this, only one participant from the H/R group felt that they did not need further information about what the clinical psychology service could offer their department. Sixty three percent of the O/N group and 85.7% of the H/R group reported that they would be interested in occasional talks by a clinical psychologist within their department.

All participants in the H/R group believed that clinical psychology had a future role to play in the care of patients in their departments. Six out of the eight participants in the O/N group believed that there was a future role. Similar patterns were observed in the responses of participants to questions about the types of future psychological involvement. Every consultant stated that one-to-one contact was possible within the hospital. Fifty percent of the O/N group felt that ward, consultancy, group and support work would be beneficial to their patients. In the H/R group 85.7% thought that ward and consultancy involvement would be beneficial and 57.1% felt that group and support work could benefit their department (Appendix 1.8).

DISCUSSION

The results of this study are now discussed in terms of the study aims.

Referral Patterns and Processes Reported by Departments

Although all departments were aware that the service existed, few could recall how they became aware of it. This suggests a lack of effective "marketing" by the Department of Clinical Psychology. The low level of perceived use of the service also supports this observation. Many departments reported that a long waiting list prevented them from referring. There was no formal item in the interview which questioned the perceived length of waiting list, but when asked informally how long they thought the waiting list to be, a number of participants thought it was more than one year and all believed it to be more than six months for all referrals. In practice, the waiting list is usually less than four

months, with most urgent referrals being seen within two days. Some years ago the waiting list was long due to staff shortages, but the length of the current waiting list has obviously not been communicated to those who found it to be a problem in the past.

Long waiting lists were identified by non-users as a barrier to referrals. A lack of information and understanding about the role of clinical psychologists was also identified as a reason for non-referral. However, very few departments believe clinical psychologists have no beneficial input to offer. This lack of understanding is perhaps reflected by the fact that non-referrers believe that a "good outcome from a previous referral" is so important in their decision to refer. Such views suggest that these departments are sceptical of clinical psychology and that its utility remains to be shown. Among the referring group a greater understanding of clinical psychology was demonstrated, as all participants identified the importance of "knowledge of a member of staff at the Department of Clinical Psychology". It is recognised that these participants believe that good communication is vital if they are to gain satisfactory input to appropriate referrals.

Level of Knowledge and Understanding about Clinical Psychology Practice as Demonstrated by Departments

The overall impression of clinical psychology within the hospital appears to reflect rather traditional attitudes towards psychological practice. In response to an open question about the work of psychologists, most participants communicated that it included the treatment of depression, anxiety, stress reactions and psychosexual problems. However, when comparing referring and non-referring groups, referring departments were aware of more recent advances in psychological input (i.e. pain management, psychological preparation for physical treatment) and were more likely to perceive these to be important in the care of their patients.

Desired maximum waiting times for treatment were generally higher than could be provided by the service. However, there was little difference between referrers and non-

referrers in terms of these preferred times. This would suggest that even though referring departments would like to see shorter waiting times they are still prepared to refer even with the current length of the waiting list. However, it could also mean that these departments are aware of the time pressures on clinical psychology department and consequently only refer priority cases. Non-referring departments, as mentioned previously, lack knowledge about the true length of the waiting list believing it to be, in some cases, more than one year. This further highlights the need for greater communication and information sharing between the Department of Clinical Psychology and other departments within the hospital.

Perception of Need for a Psychological Service as Reported by Departments

Not surprisingly, referring departments perceive a greater need for psychological input than non-referring departments. This seems to be closely related to the level of knowledge about psychological services held by members of these departments. Despite the high levels of understanding among referring departments most were still keen to hear more about further input which clinical psychology may be able to offer within their departments. This seems to reflect a more open attitude and greater interest in psychological issues.

The majority of departments were open to the possibility of involving psychologists in the care of their patients. Non-referring departments again displayed a more guarded, traditional view of how that input might occur. Such departments tended to be less keen to use clinical psychologists on the ward and were less interested in consultancy.

Assessment of Reasons For Referral/Non-Referral

Overall, the main reason for non-referral seems to be a lack of understanding about the role of clinical psychologists in hospital settings. This is compounded by very traditional views about clinical psychology and psychological issues in healthcare. Lack of knowledge about the clinical psychology service in general (i.e. waiting list times, psychological services relevant to particular departments) seems to be another salient

reason for not referring. This is exacerbated by poor communication and information sharing between such departments and the Department of Clinical Psychology.

In contrast, reasons for referral are in general the opposite of those mentioned above. Referring departments display a detailed knowledge of the psychological services they require, a very open attitude towards psychological issues in medicine and surgery and also a willingness to communicate directly with the Department of Clinical Psychology.

LIMITATIONS

The small sample of participants in this study limits the generality of the findings. A larger sample would have been desirable, but was not possible due to time constraints. Possible differences between the referring and non-referring groups may have been masked by extraneous variables. Furthermore, it would be unrealistic to suggest that the views of one consultant were a representative reflection of an entire department. The nature of the sample selection has probably yielded participants with more positive views of clinical psychology within their department. This has been taken into consideration in the interpretation of results. In short, a larger scale study may have revealed more striking results.

The design of the questionnaire was such that participants found some items difficult to respond to with certainty. For example, when asked about their views on clinical psychology within medicine and surgery (i.e. Q11), they found it difficult to generalise their views outwith their own department. This may have skewed results, whereby participants identified services they thought may be beneficial to their own department rather than to medicine in general. Nevertheless, the questionnaire adequately covered the issues pertinent to service provision.

IMPLICATIONS

These results support previous research which reported that the work of clinical psychologists is not clearly understood by some health care professionals (Osborne-Davies, 1996). Clinical psychologists need to educate these professions in order to further develop psychological services (Chadd & Svanberg, 1994). Some of the less positive views of psychology result from a lack of understanding about psychological practices (Bamgbose et al, 1980) and the tendency for some healthcare professionals to adhere strictly to the biomedical model of treatment (Broome & Llewelyn, 1995).

This study gives rise to a number of recommendations for the provision of psychological services to general hospitals. Firstly, education is vital to ensure that medical and surgical departments are made aware of relevant psychological services. Secondly, continued communication is vital. Attracting referrals from departments will be pointless if these referrals are inappropriate and are not based on a good understanding of psychological practices. Finally, a lack of understanding of the psychological service was demonstrated by a number of departments, but in most cases these representatives were keen to learn more about the service. It seems that their low referral rates relate more to this lack of knowledge rather than to antipathy towards clinical psychology in general.

CONCLUSION

Clinical psychologists and doctors alike can learn from the findings of this study. There is a growing awareness within the medical profession that psychological input can greatly benefit some groups of patients within general hospital settings. In general though, the level of understanding and knowledge of these psychological practices is still rather low. It is the task of clinical psychologists who work in these settings to appropriately market their services, to educate potential referring agents and to promote good communication with these departments. This study has shown that the majority of those interviewed

would support such steps. Through this, those who subscribe to the biomedical and psychosocial models of healthcare may further their appreciation of the strengths and weaknesses of their own approach to treatment. As a result they may find more common ground, thereby improving the level of psychological care within the setting of the general hospital.

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Table 1 - Factors involved in the decision to refer: A comparison of high/regular and occasional/non-referring departmental responses

	High/Regular		Occasional/Non		χ^2 p value
	no.	% (n=7)	no.	% (n=8)	
Waiting times for treatment	4	57.1	8	100	0.03*
Family's motivation to seek support	6	85.7	4	50	0.31
Patient's motivation to seek support	7	100	7	87.5	0.81
Presence of physical symptomatology	4	57.1	3	42.8	0.83
New diagnosis of serious illness	3	42.9	2	25	0.21
Knowledge of staff member	7	100	5	62.5	0.31
Good outcome from previous referral	4	57.1	8	100	0.04*
Other	0	0	0	0	-

* = p < .05

Table 2 - Types of services offered by the Department of Clinical Psychology as perceived by departmental representatives: A comparison of high/regular and occasional/non-referring departmental responses

	High/Regular		Occasional/Non		χ^2 p value
	no.	% (n=7)	no.	% (n=8)	
Advice about compliance	4	57.1	1	12.5	0.07
Behavioural management	7	100	4	50	0.03*
Adjustment to life events	6	85.7	5	62.5	0.31
Hypnotherapy	2	28.6	3	37.5	0.71
Pain management	3	42.9	3	37.5	0.83
Neuropsychological assessment	5	71.4	5	62.5	0.71
Relaxation techniques	7	100	6	75	0.15
Illness prevention	2	28.6	2	25	0.88
Advice about medication	1	14.3	1	12.5	0.92
Psychological preparation for treatment	5	71.4	3	37.5	0.19

* = p < .05

Table 3 - Relevance ratings as reported by departmental representatives for services offered by the Department of Clinical Psychology: A comparison of high/regular and occasional/non-referring departmental responses

	High/Regular		Occasional/Non		Mann-Whitney U p value
	Mean	SD	Mean	SD	
Advice about compliance	5.5	2.65	3	-	0.48
Behavioural management	7.6	2.15	4.5	2.65	0.08
Adjustment to life events	8	1.26	6.8	2.39	0.5
Hypnotherapy	8.5	0.71	3.7	0.58	0.07
Pain management	7.3	2.52	3.7	0.58	0.05*
Neuropsychological assessment	8	0.71	4.8	2.68	0.08
Relaxation techniques	7.6	2.15	6.3	2.25	0.18
Illness prevention	6	0.00	5.5	3.54	1.0
Advice about medication	6	-	3	-	0.32
Psychological preparation for treatment	6.2	1.64	3	1	0.03*

* = p < .05

CHAPTER 2

MAJOR RESEARCH PROJECT LITERATURE REVIEW

A Psychosocial Approach to the Understanding of Compliance with Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnoea Syndrome

Matt Wild

Department of Psychological Medicine, University of Glasgow

Prepared in accordance with guidelines for submission to
Sleep (Appendix 2.1)

SUMMARY

Obstructive sleep apnoea syndrome is a disorder of neural respiratory and upper airway function which results in repeated partial and complete occlusion of the upper airway during sleep. Symptoms primarily include excessive daytime sleepiness, cognitive difficulties and changes in mood, although this condition has also been associated with mortality through motor vehicle accidents and cardiovascular disease. The treatment of choice is continuous positive airway pressure. This is a highly effective treatment, however its efficacy depends on compliant use above a clinically specified number of hours per night. In the obstructive sleep apnoea population compliance rates have typically been found to be low, raising concerns about the long-term health of sufferers. So far, research has failed to conclusively explain low compliance rates on the basis of physical and clinical variables relating to obstructive sleep apnoea syndrome and continuous positive airway pressure treatment. In this review, a psychosocial approach to the understanding of compliance behaviour in this population is proposed. Social cognition models, which advocate that cognitive variables (i.e. beliefs held by an individual) are the primary determinant of social behaviour, have been successfully applied to other areas of health-care. There, they have helped to identify those who are likely to comply with certain forms of treatment. It is suggested that a psychosocial approach to the understanding of continuous positive airway pressure compliance rates may help to explain further variance in this behaviour.

The Nature of Obstructive Sleep Apnoea

Obstructive sleep apnoea (OSA) is a disorder of neural respiratory and upper airway function resulting in repeated partial and complete occlusion of the upper airway during sleep (Orr, 1997). This occlusion leads to numerous arousals from sleep (accompanied by loud snoring and gasping) throughout the night. Such apnoeic events are associated with reduced oxyhaemoglobin levels (Kribbs, 1997) and in turn lead to excessive daytime sleepiness (Reeves-Hoche, 1994), deterioration in cognitive performance (Greenberg et al, 1987; Findley et al, 1986) and changes in mood, such as increased irritability and depression (Engleman et al, 1993). Induced daytime sleepiness is also thought to be associated with mortality through motor vehicle accidents (Young et al, 1993) and chronic cardiovascular disease (Douglas & Polo, 1994). However, the causal link between OSA and poor health outcomes has been disputed in a review of the health effects of OSA by Wright et al (1997). It was argued that OSA is closely associated with obesity (Levinson, 1993) and old age (Ancoli-Israel, 1994) and that sleep apnoea may simply be a marker, or a symptom of obesity or old age rather than a separate disease entity. However, the systematic review did find more convincing evidence for a causal association between OSA, daytime sleepiness and vehicle accidents. Therefore, it may be that as Kryger (1994) suggests, OSA is not a disease itself, but a final common pathway of many diseases.

Treatment Options for OSA

Weight Reduction

A variety of options are available for the treatment of OSA. The majority of patients with OSA are overweight and weight loss has been shown to be effective in improving associated symptoms (Browman et al, 1984). However, weight reduction is a complex process and is notoriously difficult to manage in patients with morbid obesity.

Eliminating pharmacological elements which are known to suppress respiratory

function (i.e. alcohol, sedative medications) may also be an option, although this method is generally used as an adjunct to other interventions (Saskin, 1997).

Pharmacological Intervention

Pharmacological treatments have also been employed. Respiratory stimulant medication of the kind used in the management of asthma has not shown any systematic benefit in the treatment of OSA (Espinoza, 1987). There were a number of studies published in the early 1980s which reported that L-tryptophan (an essential amino acid involved in the regulation of the neurotransmitter serotonin) reduced the frequency of apnoeic episodes in patients with mild sleep apnoea (Schmidt, 1985). L-tryptophan though was linked with the development of eosinophilia-myalgia syndrome (a disorder characterised by symmetric and painful inflammation, and loss of elasticity in the tissues of the hands, arms, legs and feet) and the risk associated with its use was felt to outweigh the therapeutic advantages (Hertzman et al, 1990).

Dental Prosthesis

Dental appliances designed to advance the lower jaw, thereby increasing the posterior airway space, have been associated with improved treatment success (Fleetham, 1996), but large randomised clinical trials are still required to further determine the precise indications, benefits and risks of using oral appliances in the treatment of OSA.

Surgery

Surgery is also possible to achieve maxillomandibular advancement (Riley et al, 1986). Other surgical procedures such as tracheostomy and more advanced techniques such as uvulopalatopharyngoplasty have shown good success rates. However, the cost, complexity and not least the lack of acceptance of these aggressive procedures by many patients has prevented their widespread application (Saskin, 1997).

Continuous Positive Airway Pressure Therapy

The final treatment option is nasal continuous positive airway pressure (CPAP). This was developed by Sullivan et al in 1981 and has become widely accepted as the most effective choice of therapy in the treatment of OSA (American Thoracic Society, 1994; Douglas, 1998). CPAP works by forcing the airway to remain open with a constant stream of room air blown through the nose during sleep via a mask or nasal prongs. The efficacy of CPAP is not entirely unrefuted however. In their review of the literature examining the efficacy of CPAP in the treatment of OSA, Wright et al (1997) made a number of methodological criticisms of the research completed in this area. They concluded that the studies did not provide enough robust evidence to support the efficacy of CPAP and that well designed, large scale, randomised controlled trials should be conducted to objectively assess its efficacy and cost effectiveness. Another review (Australian Health Technology Advisory Committee, 1996) arrived at a more positive conclusion, suggesting that CPAP was effective in patients who displayed more than 20 apnoeas (i.e. temporary cessations of breathing) and hypopnoeas (i.e. periods during which there is a decrease in the amount of air breathed) per hour of sleep plus daytime sleepiness. Douglas (1998) also concluded positively that there is strong evidence for the efficacy of this therapy. As evidence, five articles were cited, including three as yet unreviewed articles (Engleman et al, 1997a; Engleman et al, 1997b; Badia et al, 1997; Engleman et al, 1998; Stradling et al, 1998). These five controlled studies all showed consistent improvements in symptoms and daytime function with CPAP in patients with OSA. Added to this it was suggested that Wright et al's review harboured an undisclosed conflict of interest as it was funded in part by purchasing authorities concerned about the increasing costs of sleep services and CPAP. In addition, none of the authors had clinical experience of sleep apnoea. Therefore CPAP is still considered by many to be the treatment of choice for OSA.

Treatment Compliance Issues in CPAP Therapy

Symptom reduction is dependent on, usually lifelong, nightly use of the CPAP apparatus, for approximately three hours or more (Engleman et al, 1996), as symptoms return almost immediately after one night without treatment (Kribbs et al, 1993). However, despite its success in relieving symptoms it has been demonstrated that compliance with this treatment often falls below that which is clinically effective (Waldhorn et al, 1990; Rauscher et al, 1991). Early studies relied on self-reported patient data to examine compliance rates. However, such methods were found to be substantially unreliable (Engleman et al, 1996). Covert time counters (activated when the unit is running) have been introduced to CPAP apparatus and have enabled more accurate objective measurement of compliance rates. CPAP compliance rates, utilising this method of measurement, have been reported to be as low as 50% (American Thoracic Society, 1994). This is of major concern, not only because of service cost implications, but because of the previously discussed long and short term risks to health associated with untreated OSA.

Predictors of Low Compliance Rates in CPAP Therapy

It could be suggested that the low compliance rate is not surprising, considering that CPAP is a self-administered, demanding treatment with associated constraints (e.g. being attached to the apparatus, noise, claustrophobia) and possible side effects (e.g. nosebleeds, dry throat, skin irritation from mask). A large body of research exists on the issue of compliance with CPAP. This has examined some the drawbacks of CPAP treatment, such as those mentioned above, in an attempt to explain the generally low compliance rates associated with the therapy. Collard et al (1997) reviewed this literature and stated that the research examining the determinants of primary acceptance and compliance to CPAP is contradictory. Wide variation in methodology and analysis is demonstrated in this literature. Studies have investigated the link between physical variables relating to OSA and CPAP therapy compliance rates, both as a primary research objective and also as part of a wider hypothesis regarding CPAP therapy. The

research can certainly explain some, but not all of the variance in compliant behaviour. These points can be demonstrated by summarising a small selection of the more recent relevant research (see Table 1). CPAP use has been predicted by polysomnographic severity in some studies (Rauscher et al, 1991; Meurice et al, 1994) but not others (Hoffstein, 1992; Reeves-Hoche, 1994), by sleepiness in some (Rauscher et al, 1991; McArdle et al, 1999) and not in others (Engleman et al, 1994; Kribbs et al, 1993), and by CPAP treatment side effects in some (Hoffstein et al, 1992; Rauscher et al, 1993) but not by others (Fletcher & Lockett, 1991; Pepin et al, 1995). Research has not been able to conclusively explain low compliance rates on the basis of clinical or physical variables.

Psychosocial Approaches to the Study of Health Behaviours

Before continuing to discuss additional perspectives on the problem of non-compliance in CPAP therapy, it is important to define the term compliance. Haynes (1979) defined compliance as, the extent to which a patient's behaviour coincides with medical advice. This definition reflects the biomedical model of health-care. In this model the doctor-patient relationship is based on the fact that the health-care professional holds legitimate, expert and informational power over the patient (Marteau, 1995). This approach focuses on the biological basis of pathology and largely ignores the psychological and social aspects of illness. The psychosocial model represents a different approach to health-care. This model recognises the impact that psychological and social factors can have on the course of an illness. The psychosocial model sees compliance as a complex, or series of behaviours (Ley, 1997), rather than simply a behaviour which may, or may not reflect medical advice. Further to this, Conner & Norman (1996b) included compliance within their definition of health behaviour. They defined health behaviour as any activity undertaken for the improvement of well-being.

So far, the research examining compliance rates in CPAP therapy has been driven by the biomedical model and has therefore focused on clinical and physical variables as possible determinants of eventual compliance. As yet, little attention has been paid to the psychological and social factors which may play a part in reduced rates of compliance in CPAP therapy. However, one study examined patients' pre-treatment psychological status to investigate whether psychological measures could contribute to the prediction of CPAP compliance (Edinger et al, 1994). In this study the Minnesota Multiphasic Personality Inventory (MMPI) was administered to 38 patients with OSA prior to being placed on CPAP therapy. The subjects were followed up six months later to assess their level of CPAP use and were labelled as either "compliers" or "non-compliers". Regression analysis showed that MMPI hypochondriasis and depression scales along with Body Mass Index and ratings of sleep quality and daytime sleepiness significantly contributed to the prediction of compliance ($R^2 = 0.63$). It was concluded that personality measures and subjective measures may be useful in predicting long term CPAP use.

The pre-treatment psychological status of OSA sufferers has not been further investigated directly. However, another study (Hoy et al, 1999) took psychosocial variables into account when trying to improve patient compliance. This study postulated that an intensive educational programme combined with increased nursing support might help to improve patient compliance. It was also hypothesised that CPAP use would be greater in those patients who initiated their own referral than those asked to seek help by a partner. Eighty patients took part in this prospective, randomised, controlled, parallel group trial of standard support versus intensive support for new OSA patients beginning CPAP therapy. In addition to finding that intensive support did increase compliance rates it was also demonstrated that CPAP use was greater in those who initiated their own referral ($p = 0.002$). These patients had similar baseline symptoms, sleepiness scores and apnoea/hypopnoea frequencies to the patients who were prompted by a partner to seek help. Therefore, differences in disease severity cannot explain the differences found in CPAP usage between these two groups. In

addition to this, CPAP use did not decline over time in the self-referring patients, but did decline in the partner referred group. This result was not interpreted from a psychological perspective, but provides further evidence to support the suggestion that pre-treatment psychological factors may play a role in determining eventual long-term compliance with CPAP therapy.

Compliance Issues in Other Chronic Disease

Low rates of compliance are not peculiar to CPAP therapy. Poor compliance with management advice has been reported in many other chronic diseases (Epstein & Cluss, 1982) such as diabetes mellitus (Shillitoe, 1995) which requires similar amounts of patient involvement, lifestyle change and commitment, to that of CPAP. Again, a body of biomedically based compliance literature exists, however, psychosocial factors (e.g. self-efficacy, locus of control, social support networks) have also been widely investigated in an attempt to explain the variability of compliance rates in diabetes mellitus (Kavanagh et al, 1993; Tillotson & Smith, 1996).

Psychosocially based theories, such as social cognition models have played a central role in the study of health behaviours in chronic disease. Their application will now be discussed further.

The Application of Social Cognition Models to the Study of Health Behaviours

Much of this research has focused on examining the cognitive factors which may determine the practice of a health behaviour such as complying with medical advice. A variety of models exist which hypothesise how these cognitive factors can produce health behaviours. These are collectively known as social cognition models. Social cognition models provide a framework for understanding the determinants of

behaviour. They advocate that cognitive variables are the primary determinant of individual social behaviour and most assume that these behaviours and decisions are based on elaborate, but subjective, cost/benefit analysis of the most likely outcome of differing courses of action (Conner & Norman, 1998). It is recognised that these models have made a valuable contribution to the understanding of who will reliably perform health behaviours (Marteau, 1995). So, as social cognition models have helped to further the understanding of compliance issues in other chronic diseases, it follows that similar models may be of benefit in the study of variability in compliance with CPAP treatment for those who suffer from OSA.

Health Locus of Control and Health Value

One such model, the health locus of control, has been heavily researched in the prediction of health behaviours. This construct has developed from Rotter's (1954) social learning theory, which states that the likelihood of a behaviour occurring in a given situation is a function of the individual's expectancy that the behaviour will lead to a specific reinforcement and the extent to which that reinforcement is valued. However, expectancies are not always situation specific, as individuals develop generalised expectancies through a variety of learning experiences. These generalised expectancies cut across situations. Locus of control is one generalised expectancy in Rotter's social learning theory and refers to an individual's beliefs about whether control over valued reinforcements is internal or external to that individual.

The mixed results gained from early research using Rotter's (1966) Internal -External scale to predict health behaviour led to criticisms that the Internal-External scale was too generalised and that the locus of control construct may not be unidimensional (Conner & Norman, 1998). Levenson (1974) suggested that internal (i.e. own actions) and external (i.e. environmental factors) locus of control beliefs may be orthogonal and that within external locus of control a distinction should be made between external control exerted by powerful others (i.e. health professionals) and the influence of chance (i.e. fate). This led to the development of the multiple health locus of control

scale (Wallston, 1978). Importantly, according to social learning theory, perception of control over health should only be predictive of health behaviours in those who value their health, as behaviours are dependent on both expectancy beliefs (i.e. health locus of control) and the value attached to certain outcomes (i.e. health value). So, according to this theory, in the case of insulin dependent diabetes mellitus, compliant health behaviour (i.e. carrying out the blood sugar level monitoring and insulin administration regime suggested by health professionals, so as to achieve effective glycaemic control) should be observed and predicted in those who place high value on health locus of control beliefs (e.g. effective glycaemic control is ultimately determined by the individual who has diabetes, rather than by the health professional) and health value beliefs (e.g. it is important to develop good glycaemic control so that further diabetes related symptoms can be prevented).

The overall variance in health behaviour explained by the health locus of control construct is rather low, even when combined with health value (Norman & Bennett, 1996). However, the general pattern of results has been in line with predictions that health locus of control and health value combine to predict health behaviour.

Self-Efficacy

In contrast, self-efficacy has proven to be one of the most powerful and consistent predictors of health behaviour (Wallston, 1992). This has its origins in Bandura's (1977) social cognitive theory, which posits that behaviour is a function of incentives and expectancies. Three types of expectancies have been identified. Situation-outcome expectancies which relate to beliefs about how events are linked, outcome expectancies which relate to the consequences of performing a behaviour, and self-efficacy expectancies which relate to beliefs about an individual's ability to perform the behaviour. Self-efficacy expectancies, or perceived self-efficacy, refers to an individual's belief in their capability to organise and carry out the courses of action required to deal with prospective situations. These self-efficacy expectancies are believed to be the most important component in the eventual execution of a health

behaviour (Bandura, 1991) and the self-efficacy construct has successfully been used in the prediction of a number of health behaviours, such as AIDS risk-reducing behaviours and smoking cessation (Schwarzer & Fuchs, 1996). However, the amount of explained behavioural variance has still remained rather low.

Wallston's Modified Social Learning Theory

Wallston (1992) modified Rotter's (1954) social learning theory in an attempt to explain health behaviour as a function of health locus of control, health value and self-efficacy. Self-efficacy was substituted for locus of control as the major generalised expectancy construct. In this modification, locus of control is considered to be a moderator variable. So, assuming that health is a valued reinforcer, internality (locus of control) and self-efficacy interact to predict health behaviour (see Figure 1). Internal health locus of control beliefs are therefore necessary, but not sufficient, to perform a health behaviour.

As yet this theory has not been applied to a clinical population, but considering the combined success of the constructs involved it may be a logical starting point for the application of cognitive approaches to the understanding of compliant behaviour in CPAP users. In the case of CPAP use, in line with Wallston's model, eventual long term CPAP users would be expected to display generally high levels of health locus of control, health value and self-efficacy.

Limitations of Social Cognition Models

Despite the successful application of social cognition models to a variety of health related fields this approach has received considerable criticism. The main themes of such criticism will now be reviewed.

Criticism has been made of psychological research which has aimed to investigate and measure cognitions. Issues have been raised as to whether such hidden processes can be accurately self-reported (Nisbett & Wilson, 1977). Added to this the relationship between cognitions and behaviour has been questioned. Cognitive models of behaviour assume that cognitions determine behaviour, but this relationship may not be directly causal and may be influenced by other processes or influences (Weinman et al, 1995). Again, in relation to this, social cognition models focus explicitly on cognitive variables, perhaps to the exclusion of other variables (i.e. emotional, environmental) potentially important in predicting health behaviour (Cartwright, 1979).

Practical issues regarding measurement have also been raised. A variety of measures have been used to investigate the same construct, creating difficulties in cross-study comparison and evaluation of that construct. Studies have also been criticised for paying too little attention to the reliability and validity of these measures (Marteau, 1995). In some cases cognitive theories have been incorrectly conceptualised by researchers and when data has been collated in accordance with theory it has not then been analysed in line with the theoretical predictions. The issue of specificity in measurement must also be mentioned. Criticisms have been made of studies which have used generalised instead of disease specific measures to investigate health related cognitive processes. However, more specific cognitive variables are not always better, as Winett (1985) suggested that a strict specific focus may lead to the detachment of the individual from broader environmental influences. The appropriate level of specificity must be considered and selected carefully on a study by study basis.

If social cognition theory were to be applied to the issue of compliance with CPAP therapy, the above criticisms would have to be considered. The adoption of a clear, theoretically based model and the employment of well established generalised measures to assess the major implicated constructs would go some way towards addressing such difficulties.

Advantages of Social Cognition Models

It remains that there are many advantages to using social cognition models (Confer & Norman, 1998). They provide a clear theoretical background on which to base future research. They also provide a basis for the selection and development of reliable, valid measures and an understanding of how they interact to predict health behaviours. In that these models identify variables important in the prediction of health behaviours, they also help to specify possible interventions (e.g. to increase compliance). Such approaches also add to our understanding of the cognitive processes involved in the motivation to perform health behaviours.

It is clear that social cognition models have identified important determinants of health behaviour and that continued interest in these models is justified. However, the application of these approaches to varying areas of health care, coupled with the continued development and refinement of such models is to be encouraged and may lead to better prediction of behaviour.

When trying to predict compliant behaviour in OSA sufferers who use CPAP therapy, it is apparent that the appropriate theory and psychological technology is available to allow for the effective investigation of such a process. Parallels can be drawn between the psychological issues pertinent to OSA and other chronic diseases which have benefited from the application of social cognition research, therefore supporting the need for the psychosocial evaluation of this clinical population.

Conclusions

This review has established that despite the proven efficacy of CPAP therapy in the treatment of OSA, compliance rates have been found to be unacceptably low. Research

examining possible predictors of compliance has failed to reliably identify indicators on the basis of physical and clinical variables. Social cognition models have advanced the understanding of health behaviour in other chronic illness. Similarities between these conditions and OSA would suggest that the application of such models may further the understanding of compliant behaviour in CPAP users. Available research evidence to support this view has been discussed (Edinger et al, 1994; Hoy et al, 1999). In particular Wallston's (1992) modified social learning theory may be an appropriate starting point for the investigation of psychosocial variables and their role in the prediction of compliance rates in CPAP therapy. By employing Wallston's model, further understanding would be gained into the relationships between health locus of control, health value, the self-efficacy construct and also their combined role in the prediction of a specific health behaviour. It is important, both clinically and economically, to consider and examine whether psychosocial factors can explain an amount of variance in compliant behaviour in this disease. OSA and CPAP compliance has received a great deal of research attention, but as yet existing research approaches have not led to clinically applicable conclusions.

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Figure 1 - Wallston's (1992) modified social learning theory

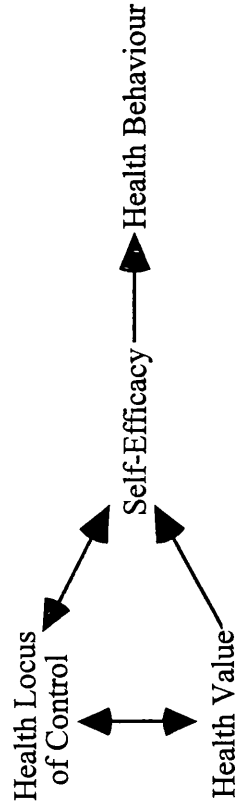


Table 1 - A summarised sample of research evidence examining predictors of CPAP compliance

Reference	Design	Main Aim of Study	Relevant Finding
Polysomnographic Severity Rauscher et al (1993)	Naturalistic, prospective study	To estimate the reliability of self-reported compliance with CPAP	Non-compliers displayed significantly lower minimum O ² saturation levels (p = .04) than CPAP compliers
Meurice et al (1994)	Naturalistic, prospective study	To study the long term acceptability of treatment with CPAP	Daily CPAP use was significantly correlated with the initial apnoea/hypopnoea index (AHI) (p = .013, r = .37)
Hoffstein (1992)	Naturalistic, prospective study	To analyse the factors that may influence patient acceptance of CPAP	No significant difference was observed between CPAP compliers and non-compliers on the basis of AHI
Reeves-Hoche et al (1994)	Naturalistic, prospective study	To document CPAP compliance	AHI did not correlate with compliance with CPAP
Sleepiness Rauscher (et al 1993)	Naturalistic, prospective study	To estimate the reliability of self-reported compliance with CPAP	Compliers displayed significantly higher initial Excessive Daytime Sleepiness scores (p = .001)
McArdle et al (1999)	Naturalistic, prospective study	To clarify the level of long-term CPAP use and the factors influencing long-term use	CPAP compliers provided significantly higher Epworth Sleepiness Scale scores (p < .0001)
Engleman et al (1994)	Naturalistic, prospective study	To study CPAP use in a British population of patients with OSA	No correlation was observed between CPAP usage and improvement in multiple sleep latency times (r = .13, p > .1)

Table 1 - continued

Reference	Design	Main Aim of Study	Relevant Finding
Kribbs et al (1993)	Naturalistic, prospective study	To determine the consequences of intermittent CPAP use	Multiple sleep latency times did not differ significantly between those who used CPAP consistently and those who used it intermittently
Treatment Side Effects Hoffstein et al (1992)	Naturalistic, prospective study	To analyse the factors that may influence patient acceptance of CPAP	CPAP compliers voiced significantly fewer adverse comments about CPAP equipment ($\chi^2 = 22$, $p < .0001$)
Rauscher et al (1993)	Naturalistic, prospective study	To estimate the reliability of self-reported compliance with CPAP	Non-compliers reported significantly more treatment side effects ($p = .05$)
Fletcher & Luckett (1991)	Naturalistic, prospective study	To examine adherence rates in a stable population of OSA patients already using CPAP	There was no significant correlation between perceived side effects and the level of compliance
Pepin et al (1995)	Naturalistic, prospective study	To systematically study the side effects of CPAP	There was no significant difference in the incidence of side effects for those who used CPAP and those who did not

CHAPTER 3

MAJOR RESEARCH PROJECT PROPOSAL

Psychological Factors Contributing to Compliance with Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnoea Syndrome

Matt Wild

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TITLE

Psychological factors contributing to compliance with continuous positive airway pressure therapy for obstructive sleep apnoea syndrome.

SUMMARY

Nasal continuous positive airway pressure (CPAP) therapy is currently the treatment of choice for obstructive sleep apnoea (OSA) syndrome. The main symptom of this chronic condition is daytime sleepiness. It is also associated with premature death as a result of cardiovascular disease and road traffic accidents. CPAP is a highly effective treatment, but is reliant on high levels of compliance. However, compliance rates for this therapy have generally been found to be low in this clinical population.

Physical variables thought to be implicated in the low compliance rates with CPAP have been investigated but have thus far failed to consistently explain a significant amount of variance in compliant behaviour. Social cognition models have been adapted to other chronic diseases, such as diabetes, in an effort to explain varying compliance rates. These approaches have met with some success in predicting future health related behaviours, but as yet have not been applied to compliance issues in CPAP therapy.

The proposed study will apply a social cognition model, incorporating the concepts of health value, health locus of control and self-efficacy, to a sample of patients who attend The National Scottish Sleep Laboratory at The Royal Infirmary of Edinburgh, in an attempt to explain variance in CPAP therapy compliance rates.

INTRODUCTION

OSA is a disorder of neural respiratory control and upper airway function resulting in repeated partial and complete occlusion of the upper airway during sleep. Although the main symptom is daytime sleepiness OSA has been linked to hypertension, ischaemic heart disease and road traffic accidents (Douglas & Polo, 1994; Simonds, 1994). CPAP is generally considered to be the treatment of choice for OSA (American Thoracic Society, 1994) due to the strong evidence of its efficacy (Douglas, 1998). However, this efficacy is dependent on the continued nightly use of the CPAP apparatus, for approximately three hours or more (Engleman et al, 1994a), as symptoms return almost immediately after one night without treatment (Kribbs et al, 1993).

Despite its success in relieving symptoms it has been found that compliance with this treatment often falls below that which provides clinical effectiveness (Waldhorn et al, 1990; Rauscher et al, 1991). A number of physical and clinical variables relating to CPAP therapy and OSA have been investigated, but have not satisfactorily explained the low rates of compliance. Such variables have included polysomnographic severity (Reeves-Hoche, 1994), prior sleepiness (Engleman, 1994b) and treatment side effects (Pepin, 1995).

As physical and clinical variables have yet to conclusively explain compliance rates, it follows that psychological variables may be implicated. Only one paper (Edinger et al, 1994) has addressed this as yet. This study employed the Minnesota Multiphasic Personality Inventory (MMPI) and concluded that the "apnea patient's pre-treatment psychological status may be useful in identifying CPAP compliers" (Edinger et al, 1994, p1118). As far as the author is aware no further research developed as a result of these conclusions.

As reported above, successful treatment of OSA requires significant dedication on the patient's behalf as this syndrome is rarely cured, therefore committing the sufferer to

lifelong treatment with CPAP. This level of involvement and commitment is required in some other chronic disorders (e.g. diabetes). A significant body of literature exists which has examined compliant behaviour in diabetes sufferers and many studies have used social cognition models as the basis for such research. Social cognition models are recognised to have made a valuable contribution to the understanding of individuals who must perform regular health related behaviours as part of an ongoing treatment for a chronic disease, such as diabetes (Marteau, 1989). Given that similar and significant lifestyle change is required for the successful treatment of both OSA and diabetes, it follows that models of health behaviour which have helped to further the understanding of compliance issues in diabetes may also help to investigate similar matters in OSA.

Social cognition models advocate that cognitive variables are the primary determinant of individual social behaviour, thereby determining whether or not an individual practices, for instance, a health related behaviour. One such model, the health locus of control construct, has been widely researched in the prediction of health behaviour. It was developed from Rotter's social learning theory which posits that "the potential for a behaviour to occur in any specific psychological situation is a function of the expectancy that the behaviour will lead to a particular reinforcement and the value of that outcome" (Rotter, 1954, p102). As a single construct, health locus of control has generally been found to explain small amounts of variance in health behaviour. Shelton et al (1992) reported that, for health locus of control beliefs to be predictive of health behaviours, an individual must value their health. This is regarded as an essential component of the motivation to perform such behaviours. The predictive power of the combination of health value and health locus of control had been reported to be rather low (Wallston, 1991), but the pattern of results was in line with the predictions of the health locus of control construct. As a result of this Wallston (1992) proposed a modified learning theory which predicted that health behaviour was determined by health locus of control beliefs, health value and self-efficacy. In this theory self-efficacy is substituted for health locus of control as the major generalised expectancy construct. The self-efficacy construct has been found to be powerfully predictive of health

behaviour and implicates cognitions regarding an individual's beliefs about their ability to respond to and control environmental demands and challenges.

As yet, Wallston's (1992) modified social learning theory has not been formally tested and social cognition models have not been applied to the issue of low compliance rates with CPAP therapy. The present study will apply this theory to a population of CPAP users in an attempt to explain the variance in compliance behaviour, on the basis of the three cognitive constructs of health value, health locus of control and self-efficacy.

AIMS AND HYPOTHESES

In Wallston's (1992) theory the locus of control is seen as a moderator variable, therefore (it is expected that) assuming health is a valued reinforcer for an individual, internality and self-efficacy will interact to predict compliance. It is proposed that health locus of control beliefs are necessary, but not sufficient to perform a health behaviour.

Hypothesis - Compliers with CPAP therapy will demonstrate significantly greater levels of health value, internal locus of control and self-efficacy than non-compliers, on measures of health value, health locus of control and self-efficacy (i.e. The Health Value Scale, The Multidimensional Health Locus of Control Scale and The Generalised Self Efficacy Scale).

More specifically, The Multidimensional Health Locus of Control Scale (see **Measures** section) predicts that compliers will gain higher scores on measures of internality, but exhibit a low score on measures of chance. The prediction for health locus of control relating to powerful others is less clear. Health locus of control involving powerful others may reflect a receptive attitude to health related advice from health professionals, but may also indicate a strong belief in a health professional's ability to cure illness

regardless of an individual's behaviours. Therefore, compliant patients will provide a profile on The Multidimensional Health Locus of Control Scale of either (i) high internality, low chance and low powerful others, or (ii) high internality, low chance and high powerful others. Non-compliers will demonstrate low scores on measures of internality.

PLAN OF INVESTIGATION

Subjects

Adult subjects will be recruited from clinics run by The Scottish National Sleep Laboratory. Inclusion criteria will include a recent clinical diagnosis of OSA syndrome, a score of > 8 on the Epworth Sleepiness Scale and an Apnoea/Hypopnoea Index of > 15 . Subjects who are involved in any other research based in the department will be excluded from the study. From the available epidemiological data on OSA it is expected that the studied sample will be 80% male, approximately 50 years old and will present with a variety of additional health problems other than that of OSA, such as respiratory and cardiac complications.

A comparable study on which to base a power calculation to determine the required sample size was not found within the OSA or CPAP literature. However, by extracting data from similar research examining compliance issues in diabetes (Kavanagh, 1993), a power calculation indicated that approximately 40 subjects per group (group 1, compliant subjects; group 2, non-compliant subjects; total = 80) would be necessary to demonstrate a significant between group difference ($p < .05$) using a one-tailed independent samples *t*-test with 0.8 power.

Measures

Compliance will be measured by covert time clocks contained inside each CPAP unit. These timers record the total hours of machine run time over the 3 month follow-up period. From this total a mean nightly use of the CPAP apparatus can be calculated.

Three questionnaires will be employed concurrent with Wallston's (1992) theory.

(i) The Multidimensional Health Locus of Control Scale - Form A (Wallston et al, 1978; Appendix 3.1). This scale provides a measure of generalised expectancy beliefs in relation to health along three dimensions, involving internality (measuring the extent to which an individual believes the locus of control is internal), chance (measuring the belief in chance or external factors in determining health outcomes) and powerful others (measuring the belief in the control over an individual's health by powerful others, particularly health professionals). The subject is asked to rate, on a scale of 1 (strongly disagree) to 6 (strongly agree), to what extent they agree or disagree with 18 health related belief statements.

(ii) The Health Value Scale (Lau et al, 1986; Appendix 3.2). This provides a general measure of the value an individual places on their health. The subject is required to indicate, along a scale of 1 (strongly agree) to 7 (strongly disagree), how much they agree or disagree with 4 health value belief statements.

(iii) The Generalised Self Efficacy-Scale (Schwarzer, 1992; Appendix 3.3). This scale assesses the strength of an individual's belief in their own ability to respond to novel or difficult situations and to deal with any associated obstacles or setbacks. The subject is asked to indicate how true they believe 10 generalised self efficacy statements to be, in relation to themselves, along a scale of 1 (not at all true) to 4 (exactly true).

Design

When the dependent variable is treated as continuous (i.e. hours of use [compliance] as measured by time clocks contained in the CPAP apparatus) the study conforms to a factorial between-subjects ANOVA design, with three independent variables (i.e. The Multidimensional Locus of Control Scale, The Health Value Scale and The Generalised Self Efficacy Scale). When the dependent variable is split categorically (i.e. discriminating between those who complied with treatment above a clinically effective threshold [> 3 hrs. per night] and those who did not use the treatment beyond that clinically effective level [< 3 hrs. per night]) the design involves between-subjects analysis of data, including χ^2 and t -tests.

Procedure

Following a diagnosis of OSA and subsequent offer of CPAP, potential subjects will be approached by sleep laboratory staff, during the evening prior to their first CPAP trial, to request their consent for inclusion in the study (Appendix 4.2). This will be done by means of an information sheet outlining the main points of the study. Subjects who agree to be involved in the study will sign a consent form and be asked by a member of staff to complete three questionnaires. This will take approximately 15 minutes. The administration of these measures will be the only additional procedure that participants will experience in comparison with other CPAP users not involved in the study. Upon completion all questionnaires will initially be stored in the National Scottish Sleep Laboratory. Once a month these questionnaires will be collected and transferred to the Department of Psychological Medicine, Gartnavel Royal Hospital, Glasgow, where coding and analysis of the data will take place.

In accordance with standard National Scottish Sleep Laboratory procedures, subjects will be followed up 3 months after starting CPAP therapy. At this time compliance data will be obtained from covert time clocks built into the CPAP apparatus which measures how long the machine has been turned on for. Compliance rates will be determined by

calculating the mean daily use of the CPAP apparatus over the 3 month follow up period.

To facilitate analysis, subjects will then be allocated to either a compliant sub-group or a non-compliant sub-group on the basis of the information extracted from the built in timers. Those in the compliant sub-group will have used their CPAP apparatus for an amount of time per night which is considered to be clinically effective (> 3 hrs. of average daily use; Engleman et al, 1994a). Those in the non-compliant sub-group will have used their apparatus for an average of less than three hours per night.

Setting and equipment

The proposed study will recruit subjects from The National Scottish Sleep Laboratory at The Royal Infirmary of Edinburgh. This department provides all the necessary equipment to diagnose and care for patients with OSA. Therefore, the only additional materials required to undertake this study are the psychological measures.

Data analysis

Compliance and questionnaire data will be coded and stored on SPSS for Windows. Analysis of the data will aim to evaluate the predictive power of Wallston's (1992) theory of health behaviour and identify the effects of health value, health locus of control and self efficacy on CPAP compliance. Analysis will initially involve a 3-Way between-subjects factorial ANOVA. This analysis will be employed to establish any statistical significance in the main effects and interactions of the three questionnaires in relation to CPAP compliance (when CPAP compliance is measured as a continuous variable). To evaluate clinical significance (significant differences between those above and below the accepted cut-off for clinically effective use of CPAP), between-subjects analysis (χ^2 and unrelated t-tests) will be employed.

PRACTICAL APPLICATIONS

CPAP therapy is a relatively expensive treatment and because it is self administered its efficacy relies on the patient's willingness to use the device as advised by health professionals. Hence, compliance should be considered to be the main determinant for successful use of CPAP.

This study aims to identify, on the basis of psychological measures, individuals who are less likely to comply with CPAP therapy. If this proves to be successful, such individuals could be identified at an early stage and isolated for more intensive medical and nursing support. The study may also help to guide the content of such educational or support based interventions so that resources may be allocated in the most efficient manner.

TIMESCALES

It is estimated that subject recruitment and data collection will begin in March/April 1999. It is hoped that each subject will be followed up after three months to assess compliance rates, therefore the collection of data and subject follow ups should be completed by February/March 2000. Collation and analysis of data will follow. The project will be written up by August 2000.

ETHICAL APPROVAL

Ethical approval has been obtained from the Lothian Research Ethics Committee for the study to take place within The National Scottish Sleep Laboratory (Appendix 3.4).

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EXPLANATORY STATEMENT

The following statement explains the discrepancies between the major research project proposal and the major research project paper.

Since this proposal was written (January, 1999) it was felt that the clinical relevance of the study could be improved by considering clinical and physical variables, in addition to psychological variables, as potential predictors of compliance with CPAP. This change was made to acknowledge and incorporate previous research evidence which had found associations between physical/clinical variables relating to OSA and compliance with CPAP.

To incorporate this change, the statistical analysis of the data was altered. ANOVA was not used as the number of potential variables involved in the analysis would not have allowed for an accurate interpretation of interactions. Having consulted with Professor Wallston a regression approach was favoured.

CHAPTER 4

MAJOR RESEARCH PROJECT PAPER

Psychological and Clinical Predictors of Compliance with Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnoea: A Prospective Study

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Prepared in accordance with guidelines for submission to
American Journal of Respiratory and Critical Care Medicine (Appendix 4.1)

ABSTRACT

Obstructive sleep apnoea (OSA) is a chronic respiratory disorder most commonly associated with excessive daytime sleepiness, although it has considerable association with increased morbidity and mortality through factors such as road traffic accidents and cardiovascular disease. Continuous positive airway pressure (CPAP) therapy is a highly effective treatment for this condition. However, compliance with this treatment has generally been found to be low. This places the OSA sufferer at increased risk of morbidity and mortality as a consequence of the above complications and associations. As yet, physical and clinical variables relating to OSA have failed to consistently explain compliance rates with this treatment. Social cognition models have been successful in explaining the motivation to perform health-related behaviours in other chronic conditions, such as diabetes. This study attempted to predict compliance with CPAP on the basis of a social cognition model. Wallston's (1992) modified social learning theory, comprising the psychological constructs of health value, health locus of control and self-efficacy, was applied. In addition, physical and clinical variables previously implicated in the prediction of compliance with CPAP were considered. Logistic regression analysis revealed that a model comprising health value, body mass index (BMI) and Epworth Sleepiness Scale scores explained a small, but significant amount of variance (6.1%). This combination of predictors explained 1% ($R^2 = .010$), 0.7% ($R^2 = .007$) and 4.4% ($R^2 = 0.044$) of the variance respectively. The model correctly identified 80% of CPAP compliers, but only 45% of non-compliers. This result supports previous findings that compliance with CPAP may be most productively researched by considering psychological, as well as physical and clinical variables. This bio-psychosocial approach is to be encouraged in other areas of medical research.

INTRODUCTION

Obstructive sleep apnoea (OSA) is primarily associated with extreme daytime sleepiness, cognitive impairment and disturbance of mood (Cheshire et al, 1992). This results in markedly reduced efficiency of daytime functioning, consequently negatively affecting daily activities such as driving (Young, 1993). In addition to the increased risk of road traffic accidents, it has been suggested that OSA may be associated with increased morbidity and mortality as a result of hypertension (Lavie, 1999), myocardial infarction (Marin & Kogan, 1988) and stroke (Mohsenin & Valor, 1995). OSA, a condition closely associated with significant morbidity and mortality, occurs in 2 to 4% of the middle aged population (Young et al, 1993) and does not remit spontaneously (Guilleminault et al, 1981), therefore it is important that long term management is established.

Continuous positive airway pressure (CPAP) therapy is currently the treatment of choice for OSA. The efficacy of this treatment has been well documented (American Academy of Sleep Medicine, 2000). CPAP works by forcing the upper respiratory airway to remain open with a constant stream of room air blown through the nose during sleep via a mask or nasal prongs. However, compliance with this slightly cumbersome treatment has been found to be low (Engleman et al, 1994b), with daily use of CPAP apparatus often falling below recommended levels (Reeves-Hoche et al, 1994). Compliance rates have been reported to be as low as 50% (American Thoracic Society, 1994). Three hours of use per night has been established as the minimum level at which clinical improvement in symptoms can be expected (Engelman et al, 1994a).

There are negative medical and financial consequences of low compliance. OSA is association with increased morbidity and mortality, and CPAP is a relatively expensive form of treatment. Therefore, much research has focused on determining the predictors of compliance with CPAP. The majority of this research has involved the examination of physical and clinical variables, such as initial disease severity and treatment side-

effects, as potential predictors of compliance (Hoffstein et al 1992; Meurice et al, 1994). However, the results of this research have been contradictory (Engleman et al, 1996) and no set of predictors has consistently explained a significant amount of variance in compliance rates. For example, CPAP use has been predicted by polysomnographic severity (i.e. initial disease severity) in some studies (Rauscher et al, 1991; Meurice et al, 1994) but not others (Hoffstein, 1992; Reeves-Hoche, 1994), by levels of pre-treatment subjective sleepiness in some (Rauscher et al, 1991; McArdle et al, 1999) and not in others (Engleman et al, 1994b; Kribbs et al, 1993), and by CPAP treatment side effects in some (Hoffstein et al, 1992; Rauscher et al, 1993) but not by others (Fletcher & Luckett, 1991; Pepin et al, 1995). Research has not been able to conclusively explain low compliance rates on the basis of physical or clinical variables.

Social cognition models advocate that cognitive variables (i.e. beliefs held by an individual about for instance the state of their health) are the primary determinant of individual social behaviour (Conner & Norman, 1998). Such models have been successfully adapted and applied to health care settings. There, they have made a valuable contribution to the understanding of which patients will reliably perform health behaviours (Marteau, 1995), such as comply with a recommended diabetic regimen (Tillotson & Smith, 1996).

Thus, as compliance with CPAP has not yet been reliably predicted by physical or clinical variables, it follows that psychological factors (e.g. social cognition models) may contribute some explanatory variance. Evidence for this hypothesis so far is limited. Edinger et al (1994) used the Minnesota Multiphasic Personality Inventory (MMPI) to evaluate OSA patients' psychological status prior to initiation of CPAP therapy. They concluded that personality measures (i.e. the MMPI) may be useful in predicting long-term compliance with this treatment. More recently, Hoy et al (1999) reported that CPAP use was significantly greater in patients who initiated their own referral for treatment of symptoms relating to OSA. This also suggests that pre-treatment psychological status may be an important predictor of compliance with CPAP.

A model proposed by Wallston (1992) incorporated three well established constructs (i.e. health value, health locus of control and self-efficacy) in an attempt to explain health-related behaviour.

The health locus of control construct, has been widely researched in the prediction of health behaviour. It was developed from Rotter's social learning theory which posits that "the potential for a behaviour to occur in any specific psychological situation is a function of the expectancy that the behaviour will lead to a particular reinforcement and the value of that outcome" (Rotter, 1954, p102). As a single construct, health locus of control has generally been found to explain small amounts of variance in health behaviour. Shelton et al (1992) reported that, for health locus of control beliefs to be predictive of health behaviours, an individual must first value their health. This health value construct is regarded as an essential component of the motivation to perform such behaviours. The predictive power of the combination of health value and health locus of control had been reported to be rather low (Wallston, 1991), but the pattern of results were in line with the predictions of the health locus of control construct. Consequently, Wallston (1992) proposed his modified learning theory which predicted that health behaviour was determined by high measured levels of health locus of control beliefs, health value and self-efficacy. In this theory self-efficacy is substituted for health locus of control as the major generalised expectancy construct. The self-efficacy construct has been found to be powerfully predictive of health behaviour and implicates cognitions regarding an individual's beliefs about their ability to respond to and control environmental demands and challenges.

In the present study, Wallston's (1992) modified social learning theory was applied to a population of patients with OSA prior to initiation of CPAP therapy, in order to investigate whether psychological factors may usefully contribute to the prediction of subsequent compliance with this form of treatment. In addition, demographic, physical and clinical data were considered as possible predictors. These variables were included

so as to take account of previous research evidence highlighting their potentially important contribution and also to avoid an unnecessary and potentially less environmentally valid focus on purely psychological factors.

METHODS

Subjects

During the twelve month study period all patients being offered CPAP by the Scottish National Sleep Laboratory were invited to participate. During this period 162 patients agreed to be involved. One hundred and twenty complete sets of data were gathered from these subjects (i.e. 74.1% of initial sample). Subjects were excluded from the study if they were found already to be participating in other current research projects in the department ($n = 4$, 2.5%). Twenty subjects (12.3%) could not be contacted following non-attendance at a follow up clinic and a further 6 subjects (3.7%) had moved outwith the catchment area of the service. Nine subjects (5.5%) filled out questionnaire based information incorrectly, or did not provide enough information to be included in the study. Three subjects (1.9%) had faulty time clocks on their CPAP apparatus. Their compliance data were not used. The follow up rate was therefore 74.1%.

Diagnosis

Patients were evaluated for possible OSA through clinical interview, physical examination and nocturnal sleep study by a physician experienced in sleep medicine. The decision to offer CPAP was based on the presence of at least two major symptoms of OSA, plus an Apnoea/Hypopnoea Index (AHI) of greater than 15 events per hour of sleep and an Epworth Sleepiness Scale score of more than 8. This measure (Johns, 1991) is an eight item self-reported rating scale (from 0 = no chance of falling asleep, to

3 = high chance of falling asleep) of how likely an individual feels they are to fall asleep in a number of every-day situations (e.g. while watching television, while sitting and talking to someone). Scores range from zero to a maximum of twenty four.

Measures

Compliance

Covert time clocks contained inside each CPAP unit were used to monitor compliance rates. The timers recorded the total run time (in hours) of each machine. These timers were read at a three month follow-up appointment so as to establish the mean nightly use of the CPAP apparatus (in hours).

Early studies investigating CPAP compliance were based on patient report, however self-reports are now considered to be unreliable for assessing CPAP use. Time clocks were used in this study to provide an objective measure of compliance as it has been demonstrated that OSA patients consistently overestimate their CPAP use (Collard et al, 1997) and that self-reports are unable to distinguish between compliers and non-compliers (Rauscher et al, 1993).

Psychological Measures

Three psychological measures were used in accordance with Wallston's (1992) modified learning theory.

The Multidimensional Locus of Control Scale - Form A (Wallston et al, 1978; Appendix 3.1). This scale provides a measure of generalised expectancy beliefs in relation to health along three dimensions, comprising internality (i.e. measuring the extent to which an individual believes the locus of control is internal), chance (i.e. measuring the belief in chance or external factors in determining health outcomes) and powerful others (i.e. measuring the belief in the control over an individual's health by powerful others, particularly health professionals). The subjects were asked to rate, on a

scale of 1 (strongly disagree) to 6 (strongly agree), to what extent they agreed or disagreed with 18 health-related belief statements. Alpha reliability for each of the scales has been reported to range from .67 to .77.

The Health Value Scale (Lau et al, 1986; Appendix 3.2). This provides a general measure of the value an individual places on their health. The subjects were required to indicate, along a scale of 1 (strongly agree) to 7 (strongly disagree), how much they agreed or disagreed with 4 health value belief statements. The internal consistency of this scale is .67 (Cronbach's alpha).

The Generalised Self Efficacy Scale (Schwarzer, 1992; Appendix 3.3). This scale assesses the strength of an individual's belief in their own ability to respond to novel or difficult situations and to deal with any associated obstacles or setbacks. The subjects were asked to indicate how true they believed 10 generalised self efficacy statements to be, in relation to themselves, along a scale of 1 (not at all true) to 4 (exactly true). The alpha reliability of this scale ranges from .82 to .93.

Procedure

The subjects involved in the study received identical treatment to other patients not recruited into the study. The only difference being that those involved in the present study were required to fill out three psychological questionnaires. On average these took ten minutes to complete.

Having been diagnosed with OSA and agreed to accept CPAP treatment, all potential subjects were given the option of participating in the current study. They were given a consent form (Appendix 4.2) and it was stressed that their decision to participate or not participate in the study would in no way affect their subsequent clinical treatment in the department. Having signed the consent form all subjects were then asked to complete the three psychological measures. This was the only additional procedure that the

participants were required to perform in comparison to other CPAP users. The psychological measures were completed prior to any experience of CPAP treatment.

Having completed the psychological measures, all patients received education about CPAP prior to a titration night (i.e. a trial night of CPAP when the specification of the apparatus is set-up for the individual user). This comprised an explanation of the treatment process by a nurse specialist, a mask fitting, an educational video and a 20 minute daytime trial with the full CPAP apparatus. CPAP treatment following this educational process was home-based. The titration night was the only hospital-based CPAP treatment procedure.

Following titration and having commenced home-based treatment, patients were contacted at home by a nurse specialist within the first two weeks of CPAP use to enquire about any on-going problems regarding the apparatus (e.g. mask-fit, nasal congestion, skin irritation). Difficulties were addressed as appropriate. All patients were then contacted three months after starting CPAP and offered a follow-up clinic appointment. At this review patients were asked about positive treatment-effects and side-effects of CPAP. Time clocks were also read at this appointment to establish the average nightly rate of use. Patients who failed to attend their clinic appointment were contacted by phone and asked to report the time clock reading themselves.

Having gained compliance data from a subject, further information was gathered from their medical notes to provide a full set of data. Further information comprised demographic (e.g. age, gender), clinical (e.g. AHI) and physical (e.g. BMI) data.

Hypotheses

It was hypothesised that, in line with Wallston's (1992) modified social learning theory, subjects who complied with CPAP therapy would display higher scores on the three psychological measures than those subjects who did not comply with CPAP therapy.

More specifically, the Multidimensional Health Locus of Control Scale predicts that compliers will gain higher scores on measures of internality, but exhibit a low score on measures of chance. The prediction for health locus of control relating to powerful others is less clear. Health locus of control involving powerful others may reflect a receptive attitude to health related advice from health professionals, but may also indicate a strong belief in a health professional's ability to cure illness regardless of an individual's behaviours. Therefore, compliant patients were expected to provide a profile on the Multidimensional Health Locus of Control Scale of either (i) high internality, low chance and low powerful others, or (ii) high internality, low chance and high powerful others. Non-compliers were expected to demonstrate low scores on measures of internality and high scores on measures of chance.

Other potential demographic, physical and clinical factors were also considered as potential predictors of compliance. However, due to conflicting previous research findings, no predictions regarding specific variables or directions of association were made.

Statistical Analysis

Potential between group differences were investigated by means of independent *t*-tests (interval data) or chi-square (nominal data) for data which were normally distributed. Mann-Whitney U tests were used to investigate differences in data which were not normally distributed (i.e. AHI, CPAP pressure, use of alcohol). These analyses were used to select potential predictors of compliance with CPAP.

The main aim of the study was to consider the predictive value of Wallston's (1992) modified social learning theory in relation to other potential predictors to establish the best set of predictors of compliance with CPAP. Therefore, the main analysis took the form of logistic regression. This type of analysis aims to predict the membership of a categorical dependent variable (in this case, compliant/non-compliant, as this is the

most clinically relevant variable) on the basis of categorical or continuous independent variables. The compliant/non-compliant split was made at 3 hrs. of use per night as this is known to be the lower threshold of clinically effective use (Engleman et al, 1994a). In this study psychological variables were first considered as possible predictors of eventual compliance, after which, physical and clinical variables (e.g. AHI, BMI, CPAP side-effects) were considered which had been implicated in the prediction of compliance in previous research. Wallston (1998) advocates a regression approach whereby the predictive variables used are continuous variables, rather than an ANOVA approach which would require the use of discrete variables.

RESULTS

Study Population

Summary demographic and clinical information on the total sample ($n = 120$) and the compliant ($n = 69$, > 3 hrs. of use per night) and non-compliant ($n = 51$, < 3 hrs. of use per night) sub-groups is presented in Table 1.

Levels of Compliance

The mean rate of compliance for the total sample was 3.6 hrs. of use per night. Using the clinically effective compliance cut-off rate (3 hrs; Engleman, et al 1994a), it can be seen that more than half of the total sample complied with CPAP treatment. Mean daily CPAP use in the compliant sub-group (5.8 hrs. of use per night) was comparable with previously reported use in a similar OSA population (McArdle et al, 1999; Mean = 5.7, Interquartile Range = 3.9 to 7.0)

Demographic Information

The population was primarily male with a mean age of 51 years. The sample was generally married and employed. Of those not working, many were retired due to ill

health. These demographic patterns were reflected in the compliant and non-compliant sub-groups and there were no significant differences between groups.

Current Medication

Almost half of the total population were receiving medication for cardiovascular disease. Twenty percent were on medication for chronic pain, with a similar proportion currently taking psychoactive medication, mostly in the form of antidepressants (SSRI). The pattern of psychoactive medication use was positively skewed in the direction of the compliant sub-group. However, no significant difference between groups was observed. It can be seen that nineteen of the total population were receiving medication for concurrent respiratory disorders.

Intervention Received

Intervention regarding CPAP side-effects and mask fit was relatively low. Five participants required an additional chin strap to prevent the mask slipping during the night. The same number was recommended to use a decongestant to address the problem of nasal stuffiness. Twelve participants required a change of mask. None of the non-compliant sub-group received the chin strap intervention.

Use of Alcohol and Tobacco

Over half of the total sample were smokers. On average they consumed around eight units of alcohol per week.

Insert Table 1 here

Selection of Potential Predictors of CPAP Compliance Based on Comparison of Compliant and Non-Compliant Sub-Group Data

Selection of potentially predictive variables for inclusion in the initial logistic regression analysis was based on Hosmer & Lemeshow (1989). They advocate a less stringent

criterion than $p < .05$ (for between group differences) for the selection of variables in the analysis so as to avoid the misinterpretation of excluded variables. They present the case that a predictive variable might be excluded from the final model even though it is highly correlated with the dependent variable, but is removed because of co-linearity with one or more of the other independent variables. So, to avoid the potential for Type II error they suggest that a $p < .20$, rather than $p < .05$, is more likely to ensure the entry of coefficients which differ from zero.

The total sample was split retrospectively into compliant and non-compliant sub-groups on the basis of compliance data. Between group differences were examined in order to select potential predictive variables for inclusion in the logistic regression analysis based on the above selection criteria.

Demographic Variables

When the demographic data from the compliant and non-compliant sub-groups were compared it was found that they generally reflected the patterns of distribution displayed by the total population. No significant differences were observed. The selection criteria for inclusion in the logistic regression analysis was not met by any of these variables.

Medication and Intervention Variables

Potential differences between the sub-groups on the basis of categorical variables were examined. No statistically significant differences were observed on the basis of these comparisons. However, it was noted that a greater number of compliers than non-compliers received a chin strap intervention ($\chi^2 = 3.8$, $p = .07$) and more compliers were receiving psychoactive medication while using CPAP ($\chi^2 = 2.5$, $p = .15$). These two variables fulfilled the selection criteria for inclusion in further analysis.

Physical Variables

Comparison of the two sub-groups in terms of physical and clinical presentation (i.e. BMI, alcohol consumption), disease severity (i.e. AHI, minimum O² saturation, Epworth Sleepiness Scale scores) and data relating to CPAP treatment (i.e. CPAP pressure) revealed that the compliant sub-group displayed higher Epworth Sleepiness Scale scores and significantly higher pre-treatment AHI ($p < .05$) and BMI ($p < .01$) values than the non-adherent sub-group (see Table 2). This suggests that the clinical effects of OSA were more severe in the compliant sub-group. However, these values were within the typical range of the OSA population and of those who attend the National Sleep Laboratory (Hoy et al, 1999; McArdle et al, 1999). The following variables met the selection criteria for inclusion in the logistic regression analysis; Epworth Sleepiness Scale scores, alcohol consumption, minimum O² saturation and BMI.

Insert Table 2 here

Psychological Variables

Comparison between the compliant and non-compliant sub-groups on the basis of psychological variables revealed no significant differences (see Table 2). However, it should be noted that the compliant and non-compliant sub-groups displayed markedly lower (i.e. up to two standard deviations below) health value scores in comparison with scores obtained from other chronic clinical and a non-clinical populations (see Table 3). These deflated score patterns were not observed in the other psychological variables. Between group comparison revealed that compliers displayed greater health value scores than non-compliers. The health value variable met the criteria for inclusion in the logistic regression analysis.

In accordance with the research hypothesis (i.e. the compliant sub-group will display generally higher scores than non-compliant sub-group on the psychological measures) a median split was used to establish a cut-off point for the psychological variables. Using

these cut-offs, subjects were then categorised, in accordance with Wallston's (1992) model, as compliant or non-compliant on the basis of their psychological profile. No significant difference between these two groups was observed on the basis of compliance data.

Insert Table 3 here

To summarise, it has been demonstrated that the study population is typical of the general OSA population and comparable with other study populations who have attended the National Sleep Laboratory. Potential important differences were found to exist between the compliant and non-compliant sub-groups on a number of physical variables and on scores of health value. Therefore, initial inclusion in the logistic regression analysis included the following variables; Epworth Sleepiness Scale score, alcohol (units. per week), AHI, minimum O² saturation, BMI, chin strap intervention, psychoactive medication and health value score (see Table 2).

Insert Table 4 here

A model was then built with the intention of establishing the combination of variables which best predicted compliance with CPAP treatment. Variables were removed if they contributed no additional explanatory variance (*R*) to the prediction of compliance. The results of this analysis are shown in Table 4.

As can be seen, a model comprising health value scores, Epworth Sleepiness Scale scores and BMI values was found to be the best predictor of CPAP compliance. The model correctly identified 80% of CPAP compliers, but correctly allocated only 45% of non-compliers. A small, but significant amount of variance was explained by the model as a whole (6.1%). Health value scores, Epworth Sleepiness Scale scores and BMI values explained 1% ($R^2 = .010$), 0.7% ($R^2 = .007$) and 4.4% ($R^2 = 0.044$) of the variance respectively. All the variables were predictive of compliance in the expected direction.

DISCUSSION

The main aim of the present study was to investigate whether psychological factors play a role in the prediction of compliance with CPAP. Results indicated that a model comprising high health value, BMI and Epworth Sleepiness Scale scores was most predictive of compliant behaviour. This result complements the findings of Edinger et al (1994), who found that 62% of the total variance in compliance with CPAP was explained by a combination of high scores on hypochondriasis and depression scales from the MMPI, high values of BMI and high ratings of subjective daytime sleepiness. This result also supports the findings of Hoy et al (1999). They reported that a major determinant of CPAP use was whether the patient or the patient's partner initiated the referral for treatment of OSA. Although this was not interpreted from a psychological perspective, it represents further evidence that non-clinical variables may contribute to the prediction of compliance with CPAP. It would seem that the health value construct may be common to all of these findings.

Health value has been posited as an essential and primary component of the motivation to perform a health-related behaviour, for example, as in this study, comply with CPAP therapy (Lau et al, 1986). Accordingly, for an individual to engage in a health-promoting behaviour they must first value their health. In the Edinger et al (1994) paper, preoccupation with health (hypochondriasis) was implicated in the prediction of compliance. It would be expected that to be hypochondriacal, one must first value one's health. In Hoy et al (1999), spontaneous health-seeking behaviour was predictive of compliance. Again, this finding would suggest that those who sought referral already valued their health. In the current study higher health value scores were associated with greater levels of compliance. Therefore, it can be seen that although labelled differently, the construct of health value could be central to all of the above findings. In other words health is highly valued by compliers in these study samples.

Despite the finding that health value is implicated in the prediction of compliance with CPAP, the work of Lau et al (1986), who have conducted most of the research in this area, would suggest that additional psychological factors should also be considered as possible motivators. This view may be supported in this study as health value explained only a small amount of the overall variance in compliant behaviour.

In line with this theory, the predictive value of Wallston's (1992) modified social learning theory (comprising health value, health locus of control and self-efficacy) was evaluated. However, as a model, it was found that this combination of psychological variables did not usefully predict compliance with CPAP in the study population. Scores obtained on measures of self-efficacy and health locus of control did not differentiate between compliers and non-compliers. These variables did not fulfil the criteria for selection in further analysis and were assumed not to be implicated in the prediction of compliance. Further research will be required to investigate other possible psychological determinants of compliance with CPAP. This may lead to the explanation of more behavioural variance, further increasing the efficiency of the predictive model proposed in this study.

Although health value was associated with the prediction of compliance, actual scores were significantly lower than those found in other populations. Behavioural theory may partly explain this finding. The concept of learned helplessness (Seligman, 1975), which describes the acquired sense that one can no longer control one's environment so that one gives up trying, may partially explain reduced health value in the OSA population. OSA is typically associated with a variety of other chronic health complaints, including respiratory and cardiovascular disease. These significant, concurrent threats to health are perhaps more serious than would be expected in the health value comparison population (i.e. ulcer clinic patients; Lau et al, 1986). Therefore, as a result of significant experience of chronic illness, the OSA population could have learned that they have limited control over their own health. In turn, this may have resulted in generally reduced concern about health-related matters (i.e. lower health value scores). However,

as in the general population, health value varies considerably. Thus, some individuals retain a relatively high health value despite their experiences, perhaps as a function of other psychological factors. These individuals represent the CPAP compliant sub-group.

This behavioural interpretation may also explain the high prevalence of depression observed in the study sample (i.e. 18.2% on psychoactive medication, as compared with 5% prevalence of depression in the general population; Sturt et al, 1984). Learned helplessness (Seligman et al, 1976), and more specifically, negative attributional style (Abramson et al, 1978) has been implicated in the development and maintenance of depression.

The inclusion of BMI and Epworth Sleepiness Scale scores in the model of compliance supports a recent finding that patients with less severe OSA are less likely to comply with CPAP treatment (Janson et al, 2000). In the present study it was found that compliers were generally less healthy and more affected by OSA (i.e. higher BMI values, greater levels of subjective sleepiness, higher initial AHI) than non-compliers. This finding would seem to argue against the above explanation that those with more experience of illness have learned to place a lower value on their health and are therefore less likely to comply with treatment. However, it may be that those with greater OSA symptoms have more to gain by complying with CPAP treatment. A clear explanation cannot be confirmed by these data, but it would seem that, as mentioned previously, health value alone does not entirely predict compliance. This behaviour would seem to be mediated by other, as yet unidentified psychological variables.

Potential criticisms of this study include a possible sampling bias resulting from the relatively low follow-up rate (74%). However, the reasons for not obtaining a full data set were unrelated to non-compliance with CPAP. For instance, non-attendance at a follow-up clinic cannot be assumed to indicate low levels of compliance. Other reasons included valid, uncontrollable, but common factors (e.g. subjects moved away from the study area, faults occurred in CPAP equipment, questionnaires were filled out

incorrectly). Furthermore, it has been demonstrated that the study sample was typical of the general OSA population and other study samples recruited from the same centre (see McArdle et al, 1999). Thus, it is unlikely that any significant sampling bias exists within the study sample.

Disease specific psychological measures were not used in this study. This may partly explain the lack of significance found in the results relating to these scales. It has been suggested that generalised measures may be less sensitive to the cognitive processes underlying a health behaviour. However, the use of disease specific measures would not have been appropriate. Firstly, the study aimed to examine predictors of CPAP compliance, not the patients' ability to cope with OSA itself. Therefore, OSA specific measures would have evaluated inappropriate cognitive processes. Secondly, at the time of measurement, patients had not used the CPAP apparatus clinically. Therefore, patients had no prior experience of the apparatus upon which to base specific beliefs. A retrospective study using disease specific measures would be possible, although the potential measurement biases relating to such a design would then be introduced.

A small amount of variance was explained by the predictive model (see *R*-values, Table 4). Alone, on the basis of statistical evidence, it would seem that this model's potential for predicting compliance with CPAP is limited. However, it can be argued that this model demonstrates clinical significance. Firstly, these results represent similar conclusions to those drawn by Edinger et al (1994). This study explained 62% of the overall variance, based on very similar variables to the present study, with only the addition of a depression scale. This is the only other study to have specifically examined pre-treatment psychological status. Secondly, despite the small amount of explanatory variance, this model correctly identified 80% of compliers making this a clinically significant result with the potential to inform clinical practice. Kendall (1999) advocates that clinical significance, not just statistical significance is an important factor to consider in the interpretation of data. However, caution must be exercised in interpreting or implementing such a finding, as the obtained results (i.e. the predictive

model) will always fit the data provided by the study sample better than the general population.

Overall, the results of this study provide further evidence that psychological factors contribute to CPAP compliance. As a consequence of these results it may be possible to implement an intervention study based on some of the above findings aimed at increasing compliance with CPAP. Findings suggest that cognitive constructs and beliefs are involved in the motivation to comply with CPAP treatment. Such constructs are not believed to be stable personality traits, but can and do change over time as a consequence of intervening experiences, such as ill-health (Wallston, 1998; Lau et al, 1986). Previous studies have demonstrated that compliance with CPAP can be improved through interventions such as intense clinical support (Hoy et al, 1999) and group education (Likar et al, 1997). However, these studies were not psychologically informed and the mechanism of improvement was not systematically evaluated. An intervention study targeting health value related cognitions, would further evaluate the role of psychological factors in compliance with CPAP and would also investigate the possibility of increasing levels of compliance through the manipulation of health-related cognitions.

In addition to highlighting the importance of psychological variables in the prediction of health-related behaviours, these results also support the need for a wider focus in medical research. By taking a bio-psychosocial approach to the evaluation of predictors of compliance with CPAP (i.e. considering psychological variables as well as physical and clinical variables), it has been possible to further the understanding of this behaviour and open up future directions for research. Such findings would not have been obtained if a restricted focus on either physical variables, or psychological variables had been implemented.

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Table 1 - Summary demographic and clinical information on the study population (n = 120) and the compliant (n = 69) and the non-compliant (n = 51) sub-groups.

Variable	Total Sample (n=120)	Compliant Sub-Grp. (n=69)	Non-Compliant Sub-Grp. (n=51)
Levels of Compliance			
Compliance (mean/SD)	3.6 (2.8)	5.8 (1.6)	.84 (.86)
Compliance (3 hr. split) (n/%)	51 (42.5% non-comp.) 69 (57.5% comp.)	n/a n/a	n/a n/a
Demographics			
Age (mean/SD)	50.6 (10.6)	51.1 (11.4)	49.9 (9.5)
Gender (n/%)	95 (74.2% male) 25 (20.8% female.)	56 (81.2% male) 13 (18.9% female)	39 (76.5% male) 12 (23.5% female)
Marital Status (n/%)	99 (82.5% marr.) 17 (14.2% single) 4 (3.3% widow.)	55 (79.7% marr.) 11 (15.9% single) 3 (4.3% widow.)	44 (86.3% marr.) 6 (11.8% single) 1 (2% widow.)
Occupational Status (n/%)	93 (77.5% emp.) 11 (9.2% unemp.) 16 (13.3% retired)	53 (76.8% emp.) 3 (4.3% unemp.) 13 (18.8% retired)	40 (78.4% emp.) 8 (15.7% unemp.) 3 (5.9% retired)
Medication			
Cardiovascular (n/%)	53 (44.2% on med.)	32 (46.4% on med.)	21 (41.2% on med.)
Psychoactive (n/%)	22 (18.2% on med.)	16 (23.2% on med.)	6 (11.8% on med.)
Pain (n/%)	24 (20% on med.)	11 (15.9% on med.)	13 (25.5% on med.)
Respiratory (n/%)	19 (15.8% on med.)	11 (15.9% on med.)	8 (15.7% on med.)
Intervention			
Mask Change (n/%)	12 (10% rec. int.)	8 (11.6% rec. int.)	4 (7.8% rec. int.)
Chin Strap (n/%)	5 (4.2% rec. int.)	5 (7.2% rec. int.)	0 (0% rec. int.)
Decongestant (n/%)	5 (4.2% rec. int.)	4 (5.8% rec. int.)	1 (2% rec. int.)
Use of Alcohol/Tobacco			
Alcohol (units per day) (mean/SD)	8.4 (11.2)	9.8 (12.6)	6.5 8.7
Current Smoker (n/%)	68 (56% smoke.)	37 (53.6% smoke.)	31 (60.8% smoke.)

Table 2 - Comparison of compliant and non-compliant sub-group data for the selection of potential predictors of CPAP compliance.

	Non-Compliant Sub-Grp. (n = 51)		Compliant Sub-Grp. (n = 69)			
Variable	Mean	SD	Mean	SD	t (U)	p value
<u>Physical</u>						
Epworth score	12.6	5.2	14.1	4.8	-1.6	.111
Alcohol (units per week)	6.5	1.2	9.8	1.5	(1502.0)	.158
AHI	37.4	26.4	51.4	39.2	(1377.5)	.043*
Min. O ² Saturation	81.5	10.7	79	10	1.3	.191
BMI	31.1	6.9	34.8	6.7	-3.0	.004**
CPAP pressure	8.4	.86	5.8	1.6	(1708.0)	.784
<u>Psychological</u>						
Self-Efficacy	30.5	4.3	29.8	4.4	.87	.385
Health Value	3.5	.98	3.7	.90	-1.12	.131 (one
HLOC Internal	24	5.4	24.8	5.3	-.80	.301 (one
HLOC Chance	18.3	6.2	18.2	6	.12	.450 (one
HLOC Powerful Others	19.4	5.4	18.8	5.7	.52	.602

* = p < .05

** = p < .01

AHI = Apnoea Hypopnoea Index; BMI = Body Mass Index

Note - Higher Epworth Sleepiness Scale scores suggest greater subjective sleepiness. Higher AHI scores suggest higher initial disease severity. Higher BMI values suggest greater body mass. Higher scores on the psychological measures of self-efficacy, health value, HLOC internal and HLOC chance were predicted to be associated with greater compliance. A prediction about the direction of association with compliance was not made for the measure of HLOC powerful others.

Table 3 - Comparison of study population with chronic clinical and non-clinical populations (psychological variables).

Variable											
Health Value *		Self-Efficacy **		HLOC Internal ***		HLOC Chance		HLOC Power. Others			
Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
<u>Population</u>											
Compliant Pop.		3.7	.90	29.8	4.4	24.8	5.3	18.2	6	18.8	5.7
Non-Compliant Pop.		3.5	.98	30.5	4.3	24	5.4	18.3	6.2	19.4	5.4
Clinical Pop.		5.6	2.6	n/a	n/a	25.8	n/a	17.6	n/a	22.54	n/a
Non-Clinical Pop.		5.7	1.0	29.2	4.6	25.5	n/a	16.2	n/a	19.1	n/a

* - Clinical Pop. = ulcer clinic patients; Non-Clinical Pop. = parents of university students (Lau et al, 1986)
** - Clinical Pop. = n/a; Non-clinical Pop. = healthy adults (Schwarzer, 1993)
*** - Clinical Pop. = chronic patients; Non-Clinical Pop. = healthy adults (Wallston & Wallston, 1981)

Table 4 - Results of logistic regression analysis and the set of variables which best predict compliance with CPAP.

Variable	Wald	Significance	R	Exp.(B)
Health Value	3.61	.057	.099	1.53
Epworth score	3.18	.074	.085	1.08
BMI	9.21	.002	.209	1.10

-2 Log Likelihood = 148.5
Model χ^2 significance, p = .002

CHAPTER 5

SINGLE CASE RESEARCH STUDY

Successful Treatment of Idiopathic Hypersomnia with Modafinil (Provagil): A Paediatric Single Case Trial

Matt Wild

Department of Psychological Medicine, University of Glasgow

Prepared in accordance with guidelines for submission to
Developmental Medicine and Child Neurology (Appendix 5.1)

ABSTRACT

Modafinil has proved to be effective in the treatment of idiopathic hypersomnia (i.e. a condition typified by extreme daytime sleepiness and associated cognitive deficits) in the adult population. Currently, there is little systematic research which has evaluated its efficacy in the paediatric population. In this case study, a 15 year old male with idiopathic hypersomnia received modafinil as treatment for his condition. A single-blind, placebo-controlled trial was conducted over a seven week period. Clinical improvement of symptoms was reported and observed during treatment with modafinil. In addition, a positive treatment effect was observed on cognitive measures of attention/concentration, vigilance, speed of information processing and reaction time. This single-case trial provides some evidence for the efficacy of modafinil in the treatment of idiopathic hypersomnia in the paediatric population. Larger scale systematic studies are recommended.

Appendix 1.1 - Guidelines for submission to *Health Bulletin*

Notes for Contributors

Papers, articles and other contributions should be sent to the Editor, Health Bulletin, Scottish Office Department of Health, Room 143, St Andrew's House, Edinburgh EH1 3DE. They must be submitted exclusively for Health Bulletin. Acceptance is on the understanding that editorial revision may be necessary. All papers are reviewed by the Editor and by peer review, referees being drawn from a panel of appropriate professionals in the NHS in Scotland. No correspondence can be entered into about articles found unsuitable and returned to authors.

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- Surname and initials of author(s)
- Title of paper
- Full name of Journal
- Year published
- Volume number
- Opening and closing page numbers

Reference to books should similarly include author's name and initials, full title, edition (if necessary), place of publication, publisher's name, year, and if required volume number, chapter number or page number.

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Reprints

One hundred reprints will be supplied free of charge. A limited extra number (for which a charge will be made) may be ordered from the Editor when the proofs are returned.

Appendix 1.2 - Semi-structured interview

Name -

Department -

Position held in department -

How long position held -

Q1 - Are you aware that The Department of Clinical Psychology offers potential input to all medical and surgical departments within the hospital?

Q2 - How did you become aware of the service?

Q3 - Please rate how important you consider the service to be to the care of patients within your department? (rating 1-10, 1= not important at all, 10= of vital importance)

Q4 - Do you refer patients to the service? If YES go to (5), if NO go to (7)

Q5 - Roughly how many patients would you refer to the service in an average year?

1-5, 6-10, 11-15, 16-20

Q6 - Do you think you are currently making full use of the service? Now go to (8)

Q7 - Do any of the following reasons identify why you may not have referred to the service in the past?

- a) You do not have enough information about psychological services offered to your department
- b) You do not have enough information about the role of clinical psychologists within the hospital
- c) You do not consider the service to be of relevance to your department
- d) You do not consider clinical psychologists to have a role in the care of patients attending medical and surgical departments
- e) You consider that waiting lists may be too long
- f) You considered referral to another agency (psychiatry, GP, social work, OT) would be most appropriate in the first instance
- g) Other (please specify)

Q8 - What would you consider to be an acceptable waiting time for a clinical psychologist to make contact with your patient, following

- a) an urgent referral
- b) a routine referral (number of days, weeks, months)

Q9 - Can you give an example/examples of services the department may offer medicine and surgery?

Q10 - Please indicate on Handout A which services you think are offered by the department.

Q11 - Please indicate on Handout B how relevant you consider these services might be to medical and surgical departments. (rating 1-10, 1= extremely relevant, 10= totally irrelevant)

Q12 - Which of the following factors do you think might be involved in your decision whether or not to refer to the service:

- a) Waiting times for treatment
- b) Family's motivation for the patient to seek psychological support
- c) Patient's motivation to seek psychological support
- d) Presence of physical symptomatology
- e) New diagnosis of a serious illness
- f) Knowledge of a member of staff at the department of clinical psychology
- g) Good outcome from a previous referral
- h) Other (please specify)

Q13 - Do you see a possible role for clinical psychology to be involved with patients in your care in the future?

Q14 - Do you see a role for a clinical psychologist in any of the following areas within your department?

- a) One-to-one patient contact
- b) Contact with patients in a ward setting
- c) Consultative role with staff in your department
- d) Work with groups of patients
- e) Support for carers and staff
- Are there any others?

Handout A

Advice about compliance with treatment
Behavioural management
Adjustment to life events
Hypnotherapy
Pain management
Neuropsychological assessment
Relaxation techniques
Illness prevention
Advice about medication
Psychological preparation for physical treatment

Handout B

Advice about compliance with treatment
Behavioural management
Adjustment to life events
Hypnotherapy
Pain management
Neuropsychological assessment
Relaxation techniques
Illness prevention
Advice about medication
Psychological preparation for physical treatment

Q15 - Do you feel you have enough information about the service?

Q16 - Would you like further information about what the service could offer your department?

Q17 - Would you be interested in occasional talks by a clinical psychologist to groups of professionals working in your department?

Q18 - Any other comments?

Appendix 1.3 - Letter sent to chief consultant (consent letter)

MW/JB

Mr. M. Wild

13/03/98

Dear

I am a psychologist currently pursuing a Doctorate in Clinical Psychology at the Department of Psychological Medicine, University of Glasgow. While at Hospital, as part of my training I am required to submit a service related research project. I have chosen to evaluate staff attitudes and perceptions of need towards the service offered by the Clinical Psychology Department at Hospital to all medical and surgical departments on issues relating to the provision of this service. This will take the form of a semi-structured interview. I am very aware of pressure of time, so the interview has been designed to last no longer than thirty minutes. Perhaps you could nominate a representative from your department to take part in this study. This person would need to have knowledge of referral practices within your department. I will contact the department soon to collect the name of the nominated representative. This project has been approved by the Head of the Clinical Psychology Department at Hospital, Dr. .

If you require any further information please do not hesitate to contact me at the department.

Thank you in advance for your interest and co-operation.

Yours sincerely,

MR. M. WILD

TRAINEE CLINICAL PSYCHOLOGIST

Appendix 1.4 - Information and instructions sent to departmental representatives

MW/JB

Mr. M. Wild

13/03/98

Dear

I am a psychologist currently pursuing a Doctorate in Clinical Psychology at the Department of Psychological Medicine, University of Glasgow. While at Hospital, as part of my training I am required to submit a service related research project. I have chosen to evaluate staff attitudes and perceptions of need towards the service offered by the Clinical Psychology Department at Hospital to all medical and surgical departments on issues relating to the provision of this service. This will take the form of a semi-structured interview. I am very aware of the pressure on your time, so the interview has been designed to last no longer than thirty minutes. You have been nominated as your department's representative as you have knowledge of referral practices within your department. I will contact you soon to arrange a convenient time for us to meet. This project has been approved by the Head of the Clinical Psychology Department at Hospital, Dr. .

If you require any further information please do not hesitate to contact me at the department.

Thank you in advance for your interest and co-operation.

Yours sincerely,

MR. M. WILD

TRAINEE CLINICAL PSYCHOLOGIST

Appendix 1.5 - Referrals to the general hospital during 1997

Department	No. of Referrals in 1997	Group
(1)General Medicine	31	H/R
(2)General Surgery	12	H/R
(3)Haematology	12	H/R
(4)Anaesthetics	09	H/R
(5)Infectious Diseases	06	H/R
(6)Neurology	06	H/R
(7)Gynaecology	06	H/R
(8)Orthopaedics	01	O/N
(9)ENT	01	O/N
(10)Urology	01	O/N
(11)Dermatology	01	O/N
(12)Radiology	00	O/N
(13)Renal	00	O/N
(14)Cardiology	00	O/N
(15)Accident + Emergency	00	O/N

Appendix 1.6 - Table summarising the services offered by The Department of Clinical Psychology as perceived by departmental representatives

	High/Regular	Ocassional/Non
	no.	no.
Neuropsychological assessment	1	0
Compliance with treatment	2	0
Depression	2	2
Anxiety	4	3
Counselling	1	0
Adjustment to life events	4	2
Psychosexual difficulties	2	1
Pain management	2	0
Extra time	0	1
Behavioural therapy	0	1

Appendix 1.7 - Table summarising the total population responses to Q10 and Q11 (i.e. beliefs about services offered by the Department of Clinical Psychology and their perceived relevance to medical and surgical departments)

	No. of Depts.	Mean Relevance Rating	SD
Advice about compliance	11	7.45	1.86
Behavioural management	2	4.5	2.12
Adjustment to life events	11	6.45	2.7
Hypnotherapy	5	5	2.5
Pain management	6	5.5	2.6
Neuropsychological assessment	10	6.4	2.5
Relaxation techniques	8	5	2.1
Illness prevention	4	5.75	2.1
Advice about medication	6	5.6	2.7
Psychological preparation for treatment	13	7	2.3

Appendix 1.8 - Table of possible future psychological involvement as suggested by departmental representatives

	H/R		O/N	
	no.	% (n=7)	no.	% (n=8)
One-to-one contact	7	100	8	100
Ward contact	6	85.7	4	50
Consultation	6	85.7	4	50
Group work	4	57.1	4	50
Support for carers and staff	4	57.1	4	50
Other	0	0	0	0

Appendix 2.1 - Guidelines for submission to *Sleep*

SLEEP

Information for Contributors

SCOPE

Original manuscripts, i.e., those that have not been published elsewhere except in abstract form, on any aspect of *Sleep* (clinical, experimental, biochemical, etc.) will be considered. Laboratory, clinical, social, and historical notes (no more than 1,000 words and two figures), announcements of meetings and awards, and book reviews are also published.

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Tables

Tables should be as few and simple as possible; they should not duplicate information given in figures.

Figures

Figures should be submitted as clear, glossy prints (three duplicate copies may be photocopies of the original art), professionally drawn and lettered, at least twice the final size and lettering large enough to be legible when reduced. The maximum final size of any figure in the printed journal will be 14 by 20 cm (5 1/2 by 8 inches). The maximum size of artwork sent should be 8 1/2 by 11 inches. Ordinate and abscissa should be labeled, calibration given, and symbols and abbreviations explained in the legends. Microphotographs may be submitted in final size. A charge may be made for an excessive number of halftone plates. On the back of each figure indicate the figure number and authors' names, and indicate the top with an arrow. Authors are required to bear the cost of reproducing figures in color.

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The text of the manuscript should be in the following form: Summary- Typed on a separate sheet, the summary should be 150 to 200 words in length and suitable for use by abstracting journals. State concisely and specifically what was done, what was found, and what conclusions were reached. Whenever possible, supply translation in French. Articles submitted in French must be accompanied by an English summary. Approximately five key words for use by abstracting services should be provided at the end of the Summary. Introduction: State the object of research with reference to previous work. Methods: Describe methods in sufficient detail so that the work can be duplicated, or cite previous descriptions if they are readily available. Information must be included indicating that clinical experiments conform to the Declaration of Helsinki and animal experiments to the policy of the American Physiological Society. Editors will refuse papers in which evidence of adherence to these principles is not apparent. Differences of opinion

will be adjudicated by the Editorial Board. **Results:** Describe the results clearly, concisely, and in logical order. When possible give the range, standard deviation, or mean error and significance of differences between numerical values. **Discussion:** Interpret the results and relate them to previous work in the field. **Acknowledgments:** The minimum compatible with the requirements of courtesy should be typed on a separate sheet. **Legends:** Figure legends, numbered sequentially, are double-spaced on a separate sheet. Give the meaning of all symbols and abbreviations used in the figure.

References

References: The journal complies with the reference style given in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (see *Ann Intern Med* 1979;90:95-9 or *Br Med J* 1979;1:532-5). References are to be cited in the text by number and numbered in the order in which they are cited. The reference section should be typed double-spaced at the end of the text, following the sample formats given below. For abbreviations of journal names, refer to List of Journals Indexed in Index Medicus (available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, U.S.A., DHEW Publication No. (NIH) 80-267; ISSN 0093-3821). Provide all authors' names when fewer than seven; when seven or more, list the first three and add et al. Provide article titles and inclusive pages. Accuracy of reference data is the responsibility of the author.

Sample References

Article:

1. Meier-Ewert K, Matsubayashi K, Benter L. Propranolol: long-term treatment in narcolepsy-cataplexy. *Sleep* 1985;8:95-104.
2. Carskadon MA, Dement WC. Sleep loss in elderly volunteers. *Sleep* 1985;8:207-21.

Book:

3. Guilleminault C, Lugaresi E, eds. Sleep/wake disorders: natural history, epidemiology, and long-term evolution. New York: Raven Press, 1983.

Chapter of a book:

4. Coleman RM, Bliwise DL, Sajben N, et al. Epidemiology of periodic movements during sleep. In: Guilleminault C, Lugaresi E, eds. Sleep/wake disorders: natural history, epidemiology, and long-term evolution. New York: Raven Press, 1983:217-30.

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Short notes may be a maximum of 6 double-spaced, type-written pages. One figure or one table may be added, and the bibliography may have a maximum of 10 references. Letters, which may include interesting case reports, should be 1 1/2 double-spaced typewritten pages at most. A maximum of 5 bibliographical references is recommended.

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Appendix 3.1 - The multi-dimensinal health locus of control scale

This is a questionnaire designed to determine the way in which different people view certain important health-related issues. Each item is a belief statement with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you disagree or agree with the statement. The more strongly you agree with a statement, then the higher will be the number you circle. The more strongly you disagree with a statement, then the lower will be the number you circle. Please make sure that you answer every item and that you circle **only one** number per item. This is a measure of your personal beliefs: obviously, there are no right or wrong answers.

Please answer these items carefully, but do not spend too much time on any one item. As much as you can, try to respond to each item independently. When making your choice, do not be influenced by your previous choices. It is important that you respond according to your actual beliefs and not according to how you feel you should believe or how you think we want you to believe.

	Strongly disagree	Moderately disagree	Slightly disagree	Slightly agree	Moderately agree	Strongly agree
1. If I get sick, it is my own behaviour which determines how soon I get well again.	1	2	3	4	5	6
2. No matter what I do, if I am going to get sick, I will get sick.	1	2	3	4	5	6
3. Having regular contact with my doctor is the best way for me to avoid illness.	1	2	3	4	5	6
4. Most things that affect my health happen to me by accident.	1	2	3	4	5	6
5. Whenever I don't feel well, I should consult a medically trained professional.	1	2	3	4	5	6
6. I am in control of my health.	1	2	3	4	5	6
7. My family has a lot to do with my becoming sick or staying healthy.	1	2	3	4	5	6
8. When I get sick, I am to blame.	1	2	3	4	5	6
9. Luck plays a big part in determining how soon I will recover from an illness.	1	2	3	4	5	6
10. Health professionals control my health.	1	2	3	4	5	6
11. My good health is largely a matter of good fortune.	1	2	3	4	5	6
12. The main thing which affects my health is what I myself do.	1	2	3	4	5	6
13. If I take care of myself, I can avoid illness.	1	2	3	4	5	6
14. When I recover from an illness, it's usually because other people (for example, doctors, nurses, family, friends) have been taking good care of me.	1	2	3	4	5	6
15. No matter what I do, I'm likely to get sick.	1	2	3	4	5	6
16. If it's meant to be, I will stay healthy.	1	2	3	4	5	6
17. If I take the right actions, I can stay healthy.	1	2	3	4	5	6
18. Regarding my health, I can only do what my doctor tells me to do.	1	2	3	4	5	6

Appendix 3.2 - The health value scale

Indicate the extent to which you agree with the following four statements, using the scale below. Write the appropriate number in the blank space to the right of each statement.

<i>Strongly agree</i>		<i>Moderately agree</i>		<i>Moderately disagree</i>		<i>Strongly disagree</i>
1	2	3	4	5	6	7

1) There is nothing more important than good health.

2) Good health is only of minor importance in a happy life.

3) If you don't have your health, you don't have anything.

4) There are many things I care about more than my health.

Appendix 3.3 - The generalised self-efficacy scale

	Not at all true	Barely true	Moderately true	Exactly true
1. I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2. If someone opposes me, I can find means and ways to get what I want.	1	2	3	4
3. It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
4. I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6. I can solve most problems if I invest the necessary effort.	1	2	3	4
7. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8. When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9. If I am in a bind, I can usually think of something to do.	1	2	3	4
10. No matter what comes my way, I'm usually able to handle it.	1	2	3	4

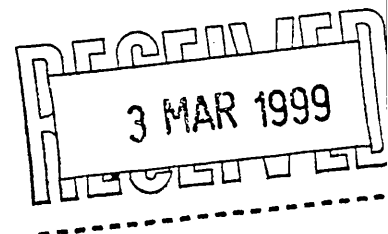
Appendix 3.4 - Lothian Region Ethics Committee clearance



OUR REF: LREC/1999/4
PLEASE QUOTE IN ALL CORRESPONDENCE

2 March 1999

Professor Neil Douglas
Respiratory Medicine Unit
Department of Medicine
Royal Infirmary of Edinburgh
Lauriston Place
Edinburgh



Dear Professor Douglas,

Request for Ethical Approval LREC/1999/4 – CPAP Compliance.

Thank you for your letter of 4 February 1999 asking if the use of psychological profiling using standard questionnaires requires a full ethical submission or not. The Chairman of the Medicine and Clinical Oncology Research Ethics Sub-Committee agrees that the use of a questionnaire as part of the clinical process of identification of which patients are more likely to use CPAP can be viewed as an extension of clinical practice. Even if the results are audited and published, the Chairman does not believe that this requires formal permission from the Sub-Committee.

Yours sincerely

A handwritten signature in dark ink, appearing to read 'Val Stewart'.

Val Stewart
Secretary
Medicine and Clinical Oncology
Research Ethics Sub-Committee

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Appendix 4.1 - Guidelines for submission to *American Journal of Respiratory and Critical Care Medicine*

AJRCCM

INSTRUCTIONS FOR CONTRIBUTORS

The AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE publishes original papers on laboratory and clinical research and clinical observations that are pertinent to respiratory biology and medicine and critical care. Only papers written in English can be considered. The JOURNAL is published in both print and electronic formats and may be viewed online at <http://www.atsjournals.org> or at <http://intl.atsjournals.org> from many countries in Europe and Asia.

SUBMISSION OF MANUSCRIPTS

Send four copies of the manuscript, four photocopies of line drawings and graphs, and four photographic prints of each halftone to:

American Journal of Respiratory and Critical Care Medicine
Editorial Office
211 West Wacker Drive
Suite 1000
Chicago, IL 60606

Authors are advised to keep one copy of the complete manuscript on file, as no manuscripts or photographs will be returned. The JOURNAL is not responsible for manuscripts lost or damaged. Four photographic prints of all illustrations will be required upon submission of revised manuscripts. One copy of the manuscript and one copy of the photographic prints will remain on file in the editorial office. Reviewers are instructed to destroy the manuscript after review. Manuscripts that do not conform to guidelines may be returned to the author.

Manuscripts are acknowledged upon receipt. When inquiring about a manuscript, refer to the number assigned the manuscript.

Manuscripts judged by the Editors to be more appropriate for consideration by the American Journal of Respiratory Cell and Molecular Biology will be transferred to that editorial office for review and potential publication. Authors will be notified of the transfer.

Be certain to list the FAX number of the corresponding author on the title page. All correspondence will be by FAX only.

HANDLING OF MANUSCRIPTS

Manuscripts are accepted for publication on the basis of scientific merit, significance, and suitability for publication in a journal devoted to clinical and laboratory studies of respiratory and critical care medicine.

One set of paged galley proofs is provided before publication of each paper and must be returned within 48 hours of receipt. Alterations are to be kept to a minimum and may be made only on the paged galley proof. Please note that changes of content and insertions of missing information will be billed to the author. An offprint order form is enclosed with the paged galley.

On publication, each report indicates the dates that the original manuscript and the revised manuscript (if necessary) were received at the editorial office.

COVER LETTER

A cover letter, signed by all the authors, listing the name, address, FAX, and telephone number (also E-mail address if available) of the corresponding author must accompany the manuscript. The cover letter must also state that no part of the research presented has been funded by tobacco industry sources. If any data are derived from subjects or animals of a previous report, this must be stated explicitly in the cover letter. This requirement applies even if the data derived from these experiments do not overlap.

The author(s) must state in this letter that the submitted material has not been published and is not being considered for publication elsewhere. Submission of a manuscript indicates tacit acknowledgment that all authors have made significant contributions to the study and have read and approved the manuscript. Any change in authorship following the original submission must be justified and agreed to in writing by the affected author(s).

In addition, an Assignment of Copyright form, signed by all authors, should accompany the manuscript. This form may be obtained from the ATS website or from the Journal Editorial Office. The form may be photocopied.

The AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE requires that any direct commercial association that might lead to a conflict of interest must be disclosed by the author(s) in the covering letter of submission. This information will be withheld from the reviewers and will not affect acceptance for publication. At the time of publication, the information will be disclosed in a footnote to the published manuscript. Less direct associations, such as consultancies, stock ownerships in an author's or relative's name, patents, etc., should be disclosed in the letter to the Editor. The extent and means of possible disclosure will be determined by discussion with the Editor following acceptance of the manuscript for publication.

PRIOR PUBLICATION

The journal does not publish original contributions that contain a significant portion of material that has been published or submitted for publication elsewhere, except for abstracts of not more than 400 words. A computer search will be conducted to ensure that submissions have not been previously published. The Editors of the JOURNAL reserve the right to determine what constitutes significant duplicate publication. If any material contained in the submitted manuscript has been published or submitted for publication elsewhere, the author(s) must include four copies of a reprint or preprint containing this material at the time of submission.

Editorials and special features clearly designated as reviews may contain previously published material as long as it is appropriately referenced. It is the responsibility of the author(s) to submit appropriate written permission to utilize previously published material that would otherwise violate copyright regulations.

HUMAN AND ANIMAL STUDIES

The AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE endorses the recommendations concerning human research that are contained in the Declaration of Helsinki. The Editors reserve the right to reject any manuscript containing studies that do not conform to these recommendations. All manuscripts reporting human research must contain a statement in the text that the protocols were approved by the institutional review board for human studies and that informed written consent was obtained from the subjects or their surrogates if required by the institutional review board.

Animal studies must conform to NIH guidelines (Guide for the Care and Use of Laboratory Animals, NIH Publication No. 86-23, Revised 1985, U.S. Government Printing Office, Washington, D.C. 20402-9325). Descriptions of surgical procedures on animals should include the name, dose, and route of administration of the anesthetic agent. Paralyzing agents are not an acceptable alternative to anesthesia and should be used only in conjunction with suitable anesthetic agents.

MANUSCRIPTS

Manuscripts should be typed in 12-point type on white bond paper 21.6 by 27.9 cm (8 1/2 x 11 in) with margins of at least 2.5 cm (1 in). Double spacing should be used throughout. All papers should be organized to include: title page, abstract, text, acknowledgments, references, figure legends, footnotes, tables, and figures. Each of these elements should begin on a separate page. Pages should be numbered consecutively, beginning with the abstract.

Title Page

Titles should be limited to 85 characters. List (1) the title; (2) the first name, middle initial, and last name of each author; (3) the name of department(s) and institution(s) to which the work should be attributed; (4) the name and address of the author to whom requests for reprints should be addressed if other than the senior author or the department of origin; (5) corresponding author's FAX and phone numbers; (6) all source(s) of support in the form of grants, gifts, equipment, and/or drugs; and (7) a

short running head of no more than 35 characters (count letters and spaces).

Abstract

The second page should carry an abstract of not more than 200 words, written as a single paragraph. It should be written for the readership of both clinicians and basic investigators and should state the hypothesis or central question of the study or investigation, the study subjects or experimental animals, observational and analytical methods, the main findings, and a final statement of the principal conclusions. Use only approved abbreviations.

Text

The text of articles should usually, but not necessarily, be divided into the following sections: Introduction, Methods, Results, and Discussion. Long articles may require subheadings within some sections to clarify the contents, especially the Results and Discussion sections. There should not be more than two levels of subheadings.

Manuscripts should be concise. Excessive length will reduce the likelihood of acceptance of the manuscript for publication.

The introduction should have a clear statement of the hypothesis or central question, any background material and supporting evidence, with an explanation of the experimental approach.

Statements referring to work in progress or in prospect that imply future publication, in the JOURNAL or elsewhere, should not be used. Unpublished work should not be cited in References, but may be cited fully parenthetically within the text. Written permission from the author for citation of unpublished work should accompany the manuscript. All cases of tuberculosis and all designators of mycobacteria should be classified according to the 1990 edition of Diagnostic Standards and Classification of Tuberculosis, published by the American Lung Association. Generic names of drugs should be used instead of trade names. The location (city, state, country) of a manufacturer listed in the text should be provided after the first reference to the manufacturer.

A laboratory or chemical term or a disease process may be abbreviated only after it has been written in full at least once with the abbreviation in parentheses immediately after it, as in interstitial lung disease (ILD). Some common terms may always be abbreviated such as PO₂, PCO₂, N₂, CO, PaCO₂, PVCO₂, SaO₂, AaPO₂, DLCO, FVC, FEV₁, etc. Other terms should be defined the first time the term is used. Abbreviations should not begin a sentence. Specialized jargon should be avoided.

Units of measurement should conform to current scientific usage and can be abbreviated when they follow a number (e.g., cm, nm, ml, g, mg, nmol, °C) but not otherwise. Unusual units should be defined.

Statistical methods must be described. The standard error of the mean (+ SEM) must be distinguished from the standard deviation (± SD).

Acknowledgments

All acknowledgments should be grouped into one paragraph and placed after the Discussion.

References

References should be limited to 35 entries, typed double spaced, should begin on a separate sheet, and be numbered in the order that they appear in the text. All author's names (do not use "et al"), complete article titles, and articles in press should be included. Supply inclusive page numbers. Submitted manuscripts which have not been accepted for publication are considered as unpublished work and should not be included in the references. If an article cited in References is in press, four copies of that article should be included with the submitted manuscript.

Use abbreviations for the names of all journals as provided in Index Medicus. Spell out the names of journals that are not listed.

A reference for the statistical methods used should be cited.

Examples of References

Journal Articles

Jones, D.A., S. Howell, C. Roussos, and R. H. T. Edwards. 1982. Low-frequency fatigue in isolated skeletal muscles and the effects of methylxanthines. *Clin. Sci.* 63:161-167.

In Press

Lakatos, E., D. L. DeMets, W. B. Kannel, P. Sortie, and P. MacNamara. 1994. Influence of cigarette smoking on lung function and COPD incidence. The Framingham study. *J. Chronic Dis.*

Abstracts

Louis, M., J.B. Thorens, and J.C. Chevrolet. 1993. Calcium-channel blockers testing for primary pulmonary hypertension associated with HIV infection (abstract). *Am Rev. Respir. Dis.* 147:A536.

Books

Snedecor, G.W., and W.G. Cochran. 1967. *Statistical Methods*, 6th ed. Iowa State University Press, Ames. 258-296.

Articles in Books

Rall, T. W. 1980. Central nervous system stimulants (continued): the xanthines. In A. G. Gilman, L. S. Goodman, and A. Gilman, editors. *The Pharmacological Basis of Therapeutics*, 6th ed. Macmillan, New York. 595-607.

Government or Association Report

U.S. Public Health Service. 1979. *Smoking and Health. A Report on the Surgeon General*. U.S. Government Printing Office, Washington, DC. DHEW Publication No. (PHS)79-50066.

Tables

Tables should be configured to fit vertically on the printed page. They will be typeset to fit a width of 3¼ inches (9 centimeters) for single column or up to 7¼ inches (18½ centimeters) for double column. Tables that do not fit into this format will be returned for reworking.

Each table should be typed double spaced on a separate sheet. Do not submit tables as photographs. Tables should be numbered consecutively, have a brief title, and be cited in text. Avoid arbitrary labels or classifications, such as groups A and B, when specific descriptors, such as "control" and "hypoxia" can be used.

All non-standard abbreviations used in each table should be explained in footnotes. For footnotes, use the following symbols in this sequence: *, dagger, double dagger, §, ll, ¶, **, two dagger, etc.

Illustrations

Four photocopies of line drawings and graphs, and four photographic prints of each halftone should be submitted with the manuscript. Four photographic prints of all illustrations, will be required upon submission of revised manuscripts.

Illustrations must be good quality, unmounted prints, sized so they can be reduced to a width of 3¼ inches (9 centimeters) for single column, and not exceeding 7¼ inches (18½ centimeters) for double column. Halftones must be on glossy paper. Line drawings need not be on glossy paper; however, they may not be photocopies. The size of the symbols and lettering should be in scale with the figure. All figures within an article should be the same point size. Multipart figures should be submitted as single composites, with each panel labeled (e.g., A, B). Labels indicating subparts of a figure (A, B, C, etc.) should be boldface and capitalized but should not be larger than the type used in the text of the published article (i.e., after the figure is reduced to fit the width of one column the labels and text in the figure should not be larger than 10 points [3-4 mm in height]). To further save space, all figure titles and explanations of symbols should appear only in the figure legend, not in the actual figure. Labels should be placed within the body of the figure, not outside it. The abscissa and ordinate of each graph should be labeled clearly. Computer-generated graphics are acceptable, as long as they provide adequate reproducibility; we reserve the right to request glossy prints and to return unacceptable configurations for additional cropping and/or vertical orientation at the author's expense. Color prints are preferred to transparencies.

COLOR

The cost of publishing color art in the JOURNAL is partially subsidized by the ATS with a portion of the costs billed to authors according to the following prices: \$650 for the first

color page and \$400 for each additional page that contains color. Lead authors with manuscripts accepted for publication will be asked to confirm in writing their acceptance and responsibility for payment of this color art billing. If the color quote is not accepted, the author must indicate whether the figure should be printed in black and white or deleted. Color prints are preferred to transparencies.

Legends for Illustrations

Legends for illustrations should convey the findings and be typed double spaced, start on a separate page with arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, each one should be identified and explained clearly in the legend.

In photomicrographs, explain internal scale and identify the method of staining.

Each figure should be cited in numerical order in the text.

Submitting Figures on Disk

Figures may now be submitted as digital files on disk. However, because of the great variety of graphics software and formats available, the digital art file may not be usable. For this reason, as well as to provide a double check of the proper image, authors must include a high quality "hard copy" produced from the digital files. The Journal reserves the right at any time to use this hard copy as camera copy rather than using the digital file. Digital figures must be submitted as TIFF or EPS files; color art may only be submitted in the CMYK format. Fonts in EPS files should be converted to "create outlines" or "convert to paths," as this will eliminate the need to download the fonts for outputting. Black and white line art must be processed at a minimum of 900 dpi (data per inch), halftones at 300 dpi, combos (color image + type, or black and white image + type) at 500 dpi, and color at 300 dpi. Images and text should be submitted on separate disks.

Please download the Guidelines for Submitting Digital Image Files from the ATS website or call the Journal Editorial Office for detailed information on resolution, file format, and other important details about digital art submission.

CASE REPORTS

The presentation of Case Reports should be similar to that of major articles, but in most circumstances should not exceed 10 typewritten pages including references.

Case Reports should provide new information concerning etiology, mechanism, or management of a disease process. Collections of several cases are more desirable than reports of single cases. The new information must be substantiated by scientific, rather than circumstantial, evidence. Reports of coexistence of two diseases or conditions without proof of casual relation are discouraged.

BRIEF COMMUNICATIONS

In general, Brief Communications are concise articles with significant new observations, whether experimental or clinical. These manuscripts should not be longer than 10 double-spaced typewritten pages including references. The format described for major articles, including illustrations and tables, should be followed.

SPECIAL FEATURES

Special features, such as Editorials, Clinical Commentaries, Pulmonary Perspectives, and States of the Art, are published after review by the Editor and, when appropriate, by one or more referees. Individuals who wish to contribute any of these features should send a written proposal to the Editor before completion and submission of the manuscript. Please note that feature articles must conform to the general guidelines for all manuscripts.

Editorials

Editorials are invited by the Editor. If you wish to write one, please send a written proposal to the Editor.

Clinical Commentaries and Pulmonary Perspectives

These review articles should not exceed 12 double-spaced, typewritten pages and may contain no more than 35 references. They may not include any previously unpublished data. Clinical Commentaries focus on the clinical aspects of a particular subject, while Pulmonary Perspectives focus on the more scientific aspects of the subject.

States of the Art

These are broad, comprehensive, scholarly works, which are considerably longer than the other types of review articles. Generally, these articles are 25-40 double-spaced, type-written pages, including references.

LETTERS TO THE EDITOR

Letters to the Editor provide a format to discuss previously published material or controversies. Presentations of unpublished investigations are not appropriate as Letters but rather should be submitted as Brief Communications which will be subject to peer review. Letters that confirm previously published material without adding significant new information are less likely to be published. Because of space limitations, priorities will be assigned to submitted Letters, and publication will depend on this priority rating.

Letters to the Editor should be no longer than 500 words (two double-spaced, typewritten pages) and should be accompanied by a signature. Titles are used with Letters to the Editor.

Illustrations and tables are discouraged. References are included parenthetically in the body of the letter unless several are cited, in which case they may be presented as footnotes. Otherwise, there are no footnotes.

DISK SUBMISSION

After a manuscript has been reviewed and the final revisions are accepted, authors are strongly encouraged to submit the final version on disk within seven days, accompanied by a hardcopy printout including the tables. On the disk's label, specify the file name, MS-DOS or Macintosh, and the word-processing software used. WordPerfect or Microsoft Word files are preferred, but all files are acceptable. Any material submitted on disk must be accompanied by hard-copy printout.

PAGE CHARGES

All manuscripts for original articles, brief communications, and case reports will be subject to page charges at the rate of \$75 per printed page. Authors will be billed for the charges. (Reprints of these instructions may be obtained from the Journal Editorial Office or from the ATS website at <http://www.thoracic.org/pubframe.html>).

American Thoracic Society

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New York, NY 10019

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Appendix 4.2 - Subject consent form

Research Study

We are currently undertaking a study in the department which aims to evaluate some of the beliefs held by CPAP users about their health and health related behaviours. It is hoped that information gained from this study will help to improve the service offered to patients who attend the department.

If you agree to take part you will be asked to complete three questionnaires which will take no longer than ten minutes to complete. Your responses will be stored for later analysis, but this process is completely confidential and will in no way affect your treatment in the department.

You are under no obligation to take part in the study and if you consent you can withdraw at any time. Refusal or withdrawal of consent will not affect your treatment in this department.

Thank you for your time.

I (name in block capitals) agree to take part in the above study. I understand that the information gained from me will be treated with complete confidentiality and will not affect my treatment.

Signed (patient)

Date

Signed (staff member)

Date